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Rehabilitation
R&D Progress

VA 1.23/3-2:

JRRD On-Line

Selected portions of the *Journal of Rehabilitation Research and Development* (JRRD) are being put on-line as part of the **VA Rehabilitation Database**, and coverage will be expanded monthly. At present, abstracts of all scientific articles, Calendar of Events, and current Publications of Interest are available to readers through **JRRD On Line**. *Rehabilitation R&D Progress Reports* for 1988 and listings of commercially available adult wheelchairs are also on-line.

Subscribers to CompuServe may access **JRRD On-Line** by typing "GO REHAB" or "GO HUD" and selecting the "Research and Development" menu option.

JRRD On-Line is a part of the **VA Rehabilitation Database**, which is being developed to provide consumer rehabilitation research news bulletins and clinical information as well as the *Journal, Progress Reports,* and other publications. A description of the **VA Rehabilitation Database** is presented on the inside back cover of this issue.

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- Personal computer
- Modem with communication software
- Subscription to CompuServe (connect time costs range from $6/hour (300 baud) to $12.50/hour (1200 baud); prices vary with baud rate)

II. **You can get help if needed:**
- VA Rehabilitation Database—write or call:

  John Bowman or Charles Mowry
  Office of Technology Transfer (110A1)
  VA Prosthetics R&D Center
  103 South Gay Street
  Baltimore, Maryland 21202
  Phone: 301-962-1800

III. **The VA Rehabilitation Database is user friendly:**
- A user friendly system is a central design feature of the database. No previous experience with computers is necessary and very little training is required. The system makes obtaining information about rehabilitation devices as easy as making a telephone call.

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- The VA Rehabilitation Database is available for use by anyone who subscribes to CompuServe.

V. **Free discount services:**
- The Office of Technology Transfer (OTT) can assist new users in obtaining limited free CompuServe time as an introductory service.

Veterans
Administration

Rehabilitation R&D Progress Reports

1988

Rehabilitation R&D Progress Reports
is a publication of
The Veterans Administration
Department of Medicine and Surgery

Rehabilitation Research and Development Service
Office of Technology Transfer (110A1)
VA Prosthetics R&D Center
103 South Gay Street
Baltimore, MD 21202

GUIDELINES FOR SUBMITTING PROGRESS REPORTS IN 1989

With the establishment of the VA Rehabilitation Database, the timing for submitting reports has expanded and will allow for reporting to be more flexible and the contents more current. The database is updated biweekly. Thus, we encourage researchers to send reports as soon as new progress is made so that their work can be updated on the database throughout the year. Additional and/or new progress reports not yet in the database will be added as they are received.

Reports added to the database will bear the date of receipt, so that authors and readers may readily identify new and/or updated material. (Date of receipt will not be included in the hard copy publication.)

PLEASE NOTE: In order for reports to be published in the 1989 issue of *Rehabilitation R&D Progress Reports*, they must be received in this office by September 15, 1989.

GUIDELINES FOR PREPARING PROGRESS REPORTS

1) Reports should not exceed 600 words. The text should contain a brief summary of the purpose, progress to date, preliminary findings and/or results over the past year, and may contain a brief statement of implications for future research, if appropriate.

Please note that reports are published solely as statements of investigators on the progress of their work and not as short research papers.

2) Reports must include the following information in addition to the text:

a) full names, titles, and addresses of the principal investigator and co-authors and the location of the research activity.

b) telephone number for the principal investigator.

c) full name and address of the sponsoring organization(s). Include the name of the director, if possible.

d) complete and accurate (i.e., exact title, author(s), publication title, volume, number, date, page numbers) references for publications resulting from the research reported; full information on patents or awards cited. (Published or accepted for publication material only.) Please limit references to publications published within the previous 2 years.

e) a list of key words relating to each report (to be used in the *Progress Reports* subject index).

3) Submit reports in typed or printed, double-spaced format, with clearly marked page numbers. If you can, please enclose a copy of the same material on diskette (nonreturnable). We can use files saved in pure ASCII format under PC-DOS or MS-DOS, either 5 1/4" or 3 1/2" diskettes. You may also send your reports to us through CompuServe Easy-Mail. Our CompuServe ID for Easy-Mail is 76703, 4267.

Address contributions to:
Rehabilitation R&D Progress Reports
Office of Technology Transfer (110A1)
VA Prosthetics R&D Center
103 South Gay Street
Baltimore, MD 21202

Veterans
Administration

Rehabilitation R&D Progress Reports 1988

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DISTRIBUTION/CIRCULATION POLICY

Rehabilitation R&D Progress Reports is distributed as an annual supplement of the *Journal of Rehabilitation Research and Development.* The mailing list is intended to cover all professionals in the rehabilitation field who are either actively involved in research, contemplate such involvement or need to remain familiar with the direction and methods of current research and the clinical application of its results.

At present, the *Journal* and the progress report annual publication are distributed free of charge, both in the United States and in foreign countries. Additions will be made to the mailing list upon request.

Editor's Note

The *Rehabilitation R&D Progress Reports 1988*, this year's annual supplement to the *Journal of Rehabilitation Research and Development*, is the sixth compilation of ongoing work in the field of rehabilitation research and engineering both in this country and abroad.

Over the past six years, *Rehabilitation R&D Progress Reports* has evolved as a unique and valuable resource for professionals in the rehabilitation field. This year we continued our efforts to improve comprehensiveness and readability. Special attention was given to increasing the accessibility of information in the progress reports through the subject index. Key words from every report have been incorporated into this year's greatly enlarged subject index. Cross-referencing makes related topics easier to identify and locate. Coverage of publications and patents resulting from completed work has expanded.

To guide us in making further improvements to the *Progress Reports*, we have developed a questionnaire, which is enclosed with this issue. Please take a few moments to complete the questionnaire and mail it back to us.

Seldon P. Todd, Jr.
Editor, *Journal of Rehabilitation Research and Development*

Electronic Publishing: A Technical Note

The organization of this publication was done on a specially-designed database. The preparation of the text documents was done in MicroSoft Word. We combined the use of the database and the word processor by writing a macro for the word processor that organized the individual reports in accordance with sorts produced by the database. Our database manager was the VA Fileman, running under Micronetics Multiuser Mumps (MSM) on a Dell PC AT. Mumps is an ANSI standard programming language. VA Fileman is a public domain database management system maintained by the Veterans Administration. The database was particularly useful in producing the table of contents, the author index, the subject index, and the sponsor index. The database structure was designed by John Bowman and Charles Moore, Technical Support Group, Office of Technology Transfer.

Rehabilitation R&D Progress Reports 1988

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Often, individual rehabilitation R&D projects represent parts of broader, overall programs of research. Program summaries are presented for organizations providing this information.

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ON THE COVER

A graphic representation of the VA SEATTLE ankle incorporated with the second generation VA SEATTLE foot. In the ankle unit, energy storage and release and three-axis motion are all accomplished via a specifically designed and developed convolution in the distal region (ankle) of the pylon. A single bolt attaches the ankle to the foot and a sanding screen between the foot and ankle prevents loosening. The ankle unit has been field-evaluated nationally and is now ready for commercial release. This project is sponsored by the VA Rehabilitation Research and Development Service and research is conducted at the Prosthetics Research Study, Seattle, WA. A progress report describing this work is on page 20. (Cover design, Holly Jellison. Illustration by Frank Vanni, VA Prosthetics Assessment and Information Center)

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A. Blindness and Low Vision

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A. Blindness and Low Vision

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C. Speech Impairment

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C. Speech Impairment

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377 Quantification and Modeling of Cognitive Development in Young Children as Exhibited in Mouse-Operated Drawing Tasks
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379 Brain Stimulation Analgesia in the Control of Chronic Pain
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I. Amputations and Limb Prostheses

A. General

Mechanism-Based Treatments for Phantom Limb Pain

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Sponsors: *VA Rehabilitation Research and Development Service (Project #A314-2RA); Department of Clinical Investigation of the US Army Medical Department*

Purpose—To determine causes and mechanisms of phantom pain and to test treatments based on identified mechanisms.

Methodology—Amputees reporting stump and/or phantom limb pain were recorded using thermographic measures of near-surface body heat and surface electromyographic measures of muscle tension. Each subject was recorded between two and four times while reporting varied pain intensities. Each subject used a body map to identify areas with phantom sensation, no sensation, and normal sensations. When decreased blood flow in the stump is related to increased burning phantom limb pain, peripheral vasodilators and temperature biofeedback are used to decrease the phantom pain. When increased muscle tension and spasms in the stump are related to episodes of cramping phantom pain, muscle relaxants and muscle tension biofeedback are used to control the pain.

Results—In the area of physiological mechanisms among amputees, there is a consistent inverse relationship between intensity of pain and stump temperature relative to the intact limb occurred for burning, throbbing, and tingling descriptions of phantom limb pain and stump pain, but not for other descriptions. There is no convincing evidence that major personality disorders are important in the etiology of chronic phantom pain. Initial evaluation of the logs indicates that phantom limb pain can be affected by the external environment.

The treatments described above have only been completed for a few of the subjects, and follow-ups are not yet complete, so the encouraging results of these initial treatments cannot be confirmed yet.

Future Plans/Implications—If our treatments continue to work after a one-year follow-up, this will be the first time effective treatments for phantom pain will be available for the vast majority of amputees.

Publications Resulting from This Research

Concurrent Variation of Burning Phantom Limb and Stump Pain with Near Surface Blood Flow in the Stump. Sherman R, Bruno G. *Orthopedics* 10:1395-1402, 1987.

Psychological Factors Influencing Chronic Phantom Limb Pain. Sherman R, Sherman C, Bruno G. *Pain* 28:285-295, 1987.

Differences Between Trunk Heat Patterns Shown by Complete and Incomplete Spinal Cord Injured Veterans. Sherman R, Ernst J, Markowski J. *Paraplegia* 25:466-474, 1987.

Phantom Pain: A Lesson in the Necessity for Carrying Out Careful Clinical Research in Chronic Pain Problems. Sherman R, Ernst J, Barja R, Bruno G, *J Rehabil Res Dev* 25(2):vii-x, 1988.

Treatment of Post-Amputation and Phantom Limb Pain. Sherman R, Barja R, in *Current Therapy of Pain*, K. Foley, R. Payne (Eds.), Ontario: B.C. Decker, 1988.

The Relationship Between Situational Stress and Phantom Limb Pain: Preliminary Analysis. Arena J, Sherman R, Bruno G, Smith J, *Biofeedback and Self Regulation*, abstract (in press).

Blood Velocity and Spectra Estimation from Doppler Ultrasound

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A372-RA)*

Purpose—This investigation was initiated to improve the accuracy and computational efficiency of blood flow velocity determinations from measurements obtained with pulsed Doppler ultrasound instrumentation by applying autoregressive methods of signal processing to the Doppler quadrature signals. Doppler velocity signals have proven useful in the detection of arterial diseases, such as atherosclerosis in the carotid artery which can lead to stroke.

Ultrasound is transmitted transcutaneously into blood vessels, and the reflected waves undergo a frequency shift that is proportional to the velocity of moving blood cells. This frequency change is analyzed to estimate the range of velocities. Present methods of analyzing Doppler data employ Fast Fourier Transform (FFT) algorithms for spectral and velocity estimation, and these suffer from significant limitations of resolution and accuracy when applied to blood velocity data. Advances in velocity and spectral estimation should allow improvements in the noninvasive detection and quantification of atherosclerotic plaques.

Results—Under well-controlled experimental conditions, where the true flow velocity is known, the performances of the autoregression spectral estimators and the Fourier transform technique have been evaluated for various record durations, flow velocities, and velocity estimation techniques. Results demonstrate significant improvement in the velocity estimate for low model order autoregression over the Fourier technique. The optimal record duration for the autoregression was approximately 4 to 8 ms.

It has been further found that if the entire spectrum of the Doppler ultrasound signal is to be estimated, a high model order autoregression model gives superior results in terms of spectral bandwidth than does the Fourier transform. This is of interest because spectral broadening has been studied by numerous investigators as a diagnostic aid.

Future Plans—In further studies, more complicated flows will be investigated. These include flows in which turbulence and vortex shedding are present. The nature of the spectral estimates and their relation to the Doppler signals will be studied in more detail through the use of a simulated signal recently developed by our group. This simulated signal includes within it the Doppler ambiguity inherent in measured signals, but it is useful because all the parameters, including the ambiguity statistics, are known *a priori*.

Publications Resulting from This Research

Pulsed Doppler Velocity Estimation via Autoregression and Fourier Transform. Jones SA, Giddens DP, *World Congress on Medical Physics and Biomedical Engineering (Proceedings)*, San Antonio, TX, 1988.

Estimation with Fourier Transform and Autoregressive Techniques. Davet D, Jones SA, Giddens DP, *World Congress on Medical Physics and Biomedical Engineering (Proceedings)*, San Antonio, TX, 1988.

Assessment of Cutaneous Microcirculation

This study consists of three parts: I. Permeation of Inert Gases Through Human Skin: Modeling the Effect of Skin Blood Flow; II. Reproducibility of Laser Doppler Velocimetry (LDV) Responses to Skin Temperature Changes in Normal Subjects; and, III. Assessment of Cutaneous Microcirculation (Project Extension). Each is listed on the following pages.

Permeation of Inert Gases Through Human Skin: Modeling the Effect of Skin Blood Flow

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A335-RA)*

Purpose—The purpose of this study was to develop an analytical model that determines the effects of skin perfusion (vasculature and flow rates) on the flux of inert gases through human skin.

Progress—In developing this model, we included the effects of geometry, blood flow rates, dermal resistance, and stratum corneum resistance on permeation through the skin. This gave us the dependence of gas permeation on details of skin blood flow, deep tissue conditions, tissue-blood partition coefficient, tissue diffusivity, and stratum corneum resistance. We modelled the diffusion of permeant from blood as it passed through a systematically-specified, 3-dimensional network of vessels. At any location, diffusion from the blood vessels depends on the concentrations in the surrounding tissues. These concentrations, in turn, depend on the neighboring blood vessels. As permeant diffused from vessels, we evaluated the time dependent changes of blood concentrations and the attendant fluxes of permeant through the skin. The vessel branching, vessel dimensions, vessel locations, tissue diffusivity, and stratum corneum resistance can be specified independently. This requires that all blood flow be concurrent. For our studies, we used a simplified description of vasculature to enable us to systematically compare the effects of blood flow at different depths in the skin.

Results—We examined the effects of specific changes of blood flow to subdermal, mid-dermal, and subpapillary vessels on the steady state, transcutaneous fluxes of helium, argon, xenon, and heat. These results indicate that at low total blood flow, mid-dermal and subpapillary blood flows have little effect on helium flux, but as total blood flow increases, first mid-dermal and then subpapillary flows become important. For the less permeable gases, argon and xenon, superficial blood flow becomes important at lower total blood flows. From a single measurement of gas flux at the skin surface, it is impossible to determine an unambiguous value for the underlying blood flow. Correspondingly, limited information can be derived from simple lumped parameter models, as are the basis for the usual perfusion models found in the literature, and different measurement techniques might be expected to yield different values for blood flow. However, the dependence of both gas flux on gas diffusivity in the viable tissues and skin blood flow suggests that details of skin blood flow could be revealed by simultaneously measuring the fluxes of different gases. Our results also indicate that for physiologically realistic blood flows, stratum corneum resistance has a linearly additive effect on gas flux from the skin relative to the effects of blood flow limitations and dermal resistance. This indicates that stratum corneum resistance can be evaluated *in vivo* by comparing the fluxes before and after removing stratum corneum.

Implications—As experimental methods for evaluating skin blood flow become increasingly refined and quantitative, it will become more important to consider which of the components of skin blood flow the experimental techniques measure. Mathematical modeling techniques, such as those presented here, form a basis for comparison of different experimental techniques, and can suggest further avenues of investigation for the experimental measurement of skin blood flow.

Reproducibility of Laser Doppler Velocimetry (LDV) Responses to Skin Temperature Changes in Normal Subjects

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A335-RA)*

Purpose—The purpose of the study was to estimate the intersubject and skin site variability of the Laser Doppler Velocimetry (LDV) response to skin temperature changes in normal subjects.

Progress—The response of LDV to increases in skin temperature appears to be a promising clinical test for compromised skin blood flow. To further explore the limits of this technique, we have examined the variability of the LDV temperature stress test in normal, healthy volunteers. We estimated the variance between subjects for a given skin site, and the variation between skin sites in a given subject (for a group of subjects). We also compared the use of two temperatures versus the use of three temperatures for the LDV temperature stress test.

Methodology—All studies were on normal, healthy volunteers. We used a heated skin probe (either the commercially available Medex plastic probe or a specially constructed and more accurate metal probe) to control skin temperature. Maximum LDV changes (i.e., peak responses) with skin temperature are empirically modeled as an exponential dependence; the exponential coefficient is determined by regression analysis.

Results—In the first study, we examined intersubject variability when the LDV temperature stress test was performed using only two temperatures (32 and 40) at two different sites: volar aspect of the forearm and dorsum of the foot using the Medex temperature probe, with the following results: forearm site—number of subjects: N = 15 (mean .302, standard error [SE] .0245); dorsum site—N = 17 (mean .273, SE .0284). In the second study, we compared the LDV temperature stress test among different skin sites: upper arm, forearm, medial and lateral aspects of the calf, dorsal aspects of the foot and the great toe, using the Medex temperature probe with temperatures of 32, 38, and 42 with the following results: upper arm—N = 23 (mean .191, SE .0025, standard deviation [SD] .057); forearm—N = 32 (mean .217, SE .0126, SD .071); medial calf—N = 15 (mean .190, SE .0134, SD .052); lateral calf—N = 14 (mean .195, SE .0142, SD .053); dorsum (foot)—N = 25 (mean .203, SE .0106, SD .053); great toe—N = 12 (mean .193, SE .0219, SD .076). In the third study, we measured the variability of the LDV temperature test between subjects for a given skin site at three temperatures (36, 39, and 42) using our metal temperature probe with the following results: forearm—N = 19 (mean .249, SE .0177, SD .077).

Implications—The LDV temperature stress test is remarkably reproducible between normal subjects and shows minimal dependence on skin site for normal subjects. The high degree of reproducibility for normal subjects enhances the technique's ability to detect compromised skin blood flow.

Publications Resulting from This Research

Response of Cutaneous Velocimetry to a Temperature Change: Normal and Dysvascular Patients Compared. Neufeld GR, Reilly CA, Galante SR, Roberts AB, Baumgardner JE, Graves DJ, Quinn JA, *Vasc Surg* 21:331-338, 1987.

Laser Doppler Velocimetry (LDV) Response to Skin in Temperature Changes Compared to Quantitative Perfusion Fluorometry (QPF) as a Predictor of Amputation Healing

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A335-RA)*

Purpose—The purpose of this study was to compare the abilities of the LDV temperature test and QPF in predicting the successful healing at an amputation site.

Progress—After obtaining Human Studies approval, we performed the LDV temperature stress test (as described in Parts One and Two of this report) at proposed sites of amputation in 26 informed patients prior to their undergoing a total of 36 amputations of which 24 healed and 13 failed. Each of these patients also consented to QPF prior to surgery. Patients were followed post amputation and retrospectively grouped into successful amputation (healed) or failed amputation.

Results—Mean and 95 percent confidence intervals for both groups for both tests were as follows: for the LDV Temperature Stress Test at the sites of amputation, the results were: at the 24 healed sites, there was a mean of .141, with a 95 percent confidence level (CL) of .039, and at the 13 failed sites, the mean was .066 with a 95 percent CL of .015. For the QPF at the sites of amputation, the results were: at the 24 healed sites, there was a mean of 67 with a 95 percent CL of 8.69, and at the 13 failed sites, the mean was 52 with a 95 percent CL of 12.91.

Implications—QPF has already been shown to be an effective predictor of amputation healing. The LDV temperature stress test shows potential as a more sensitive and specific predictor of amputation healing and warrants further investigation in a prospective study.

Publications Resulting from This Research

Fluorometric Quantification of Low-dose Fluorescein Delivery to Predict Amputation Site Healing. Silverman DG, Roberts AB, Reilly CA, Brousseau DA, Norton KJ, Bartley BA, Neufeld GR. *Surgery* 101:335-341, 1987.

Assessment of Cutaneous Microcirculation (Project Extension)

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A335-2RA)*

Purpose—Poor skin perfusion is a major cause of morbidity in the veteran population, resulting in high failure rates (20 to 30 percent) of lower extremity amputations and delayed rehabilitation of patients with peripheral vascular disease and diabetes. The ability to quickly and accurately evaluate the cutaneous microcirculation would provide a mechanism for predicting skin viability following surgery, or other treatment modalities.

The viability of skin depends upon the adequacy of the major blood supply which can be evaluated through angiography, plethysmography, and segmental blood pressures. Skin survival then depends upon the capacity and status of its microcirculation.

A number of investigators, including our own, have shown that the cutaneous microcirculatory response to an applied local stress (e.g., temperature or pressure) is often severely reduced in patients with dysvascular extremities.

The research outlined in this proposal is a multi-disciplinary, multi-project to achieve the following objectives: 1) Improve our helium flux skin blood flow (HFBF) method by: a) speeding up its response time to enable dynamic continuous measurement of blood flow and develop an *in vivo* determination of stratum corneum diffusional resistance; and, b) measuring quantitatively the optical properties of stratum corneum *in vitro* as a function of temperature, and develop a method for relating directly, helium flux blood flow to laser Doppler velocimetry (LDV) blood flow, and thereby obtain absolute blood flow from the LDV method. 2) Continue to evaluate multiple skin blood flow techniques (HFBF, LDV and Quantitative Perfusion Fluorometry QPF) in patients and volunteers. 3) To systematically evaluate the microcirculatory response to local temperature and applied pressure or tourniquet response as a means of predicting its short term viability, improvement with various treatment modalities and long-term rehabilitative capacity in patients and volunteers.

Introduction of the Use of Fiberglass in Prosthetics

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Sponsor: *Nevedac Prosthetic Centre*

Purpose—Experience has shown that prosthetic and orthotic appliances should be lightweight, strong, and have a good cosmetic appearance. They should also be comfortable and easy for patients to use. Our objective was to demonstrate that fiberglass is suitable for this purpose. Fiberglass-reinforced plastic (FRP) is a technique that combines glass reinforcements and polyester resins. It is non-corrosive, and the technology requires inexpensive and simple tools.

Progress—Fiberglass dies were fabricated in various sizes for elbow cups, forearm pieces, and upper extremity prostheses. Dies were also fabricated for lower extremity prostheses for the knee-piece, shin-piece, and foot-piece in various sizes. Thus we successfully made FRP component parts for both upper and lower extremity prostheses. Similarly, some orthotic devices, such as spinal back rest plates and foot orthoses, were also fabricated. The advantageous characteristics of the FRP parts became apparent when they were clinically tested on a number of patients in our institution.

The procedures used for measurement and cast modification are the same as the procedures used for plaster casts. However, layers of fiberglass are reinforced into prosthetic sockets to gain additional strength. The sockets are then aligned over the prefabricated FRP component parts.

Results—Encouraging results were demonstrated with the FRP component parts. Results were even more encouraging with the patients who were already wearing prostheses made by conventional techniques of wood-plastic lamination. They unanimously commented that the prostheses made with FRP parts were much lighter in weight. The FRP prostheses have been in use for over a year now, and the general assessment has been that they are much stronger and lighter in weight than earlier versions. Depending on the physique of the patient, the average weight of the PTB prostheses with FRP parts has been assessed at between 1 to 2 kilograms, while the above-knee and hip disarticulation prostheses weigh between 2.5 to 4 kilograms.

Another advantage is that, after satisfactory gait training, the lower-limb prostheses require only a few hours for final finishing, since most of the prostheses are 80 percent prefabricated. Polyurethane foam coating is applied to them and pigmented resins are used to obtain the desired color. Thus a cosmetic finish is achieved, and though the prostheses appear sophisticated, they have been developed through an uncomplicated and inexpensive technology. This is very important because the cost factor is a major consideration in a developing country like India.

Future Plans/Implications—Future plans include further exploration into the use of fiberglass in the creation of prosthetic and orthotic appliances. As FRP has ample scope in design flexibility, a much wider range of manufacture of FRP prosthetic orthotic devices is envisaged. In advanced nations, computer-aided design and computer-aided manufacture (CAD/CAM) may be possible in this respect. However, as far as India is concerned, though highly sophisticated and very expensive technology may not be possible, there is enough room for reasonably sound technology to be utilized in the production of such prosthetic/orthotic devices. Therefore, since practically all the types of machinery, equipment, and raw materials are available in India for this process, our future plans are based on the manufacture of these reasonably sophisticated prosthetic and orthotic devices.

Computerized Design and Manufacturing Methods for Prosthetics and Orthotics

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—One of the research directions currently underway in some laboratories is the application of computer-aided design and computer-aided manufacturing (CAD/CAM) methods to the field of prosthetics and orthotics. In fact, two different groups have already released CAD/CAM systems for below-knee prostheses for commercial marketing. These two systems use some unorthodox prosthetics practices, yet seem to work. The apparent success of these systems has helped to remind us that not much is known about the science of prosthetics and orthotics; about why it is that a particular socket design does or does not work. The purpose of this project is to investigate some of the fundamental mechanics which govern the interaction between the human body and prosthetic and orthotic devices. To this end, the project includes: 1) Investigation into the role of shape and compliance in the human/device interface. This includes development of a device and methodology for the *in vivo* characterization of body surface topography and surface stiffness. The digital input device is designed around the requirements of this research project but also in consideration of the clinical environment of the prosthetics-orthotics laboratory for future CAD/CAM applications. 2) The mechanics of the human/device interface will be investigated using computer models. The effects of device shape and compliance on the magnitude and distribution of tissue stresses and skeletal loading will be investigated. 3) Finite-element analysis of various above-knee (A/K) socket designs will be compared with clinical measurements as a means of validating the models and their prediction of human/device interaction. The goal is then to expand the model into a socket design tool utilizing tissue stresses as design criteria.

All measurements of body surface topography and surface stiffness will be compiled into a 3-dimensional anthropometric database.

Continuing investigations of new technological advancements in computer-based analysis, design, and manufacturing methods will be made for their application to prosthetics and orthotics.

Progress—Design of the digital input device for body structural characterization is proceeding. We have just received delivery of an engineering workstation and are working to set up the modeling software for mechanical analysis. Generic representations of the A/K amputated limb have been constructed and elementary mechanical modeling has begun.

Prosthetic/Orthotic Materials

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Purpose—There is a need to employ currently accepted, standardized testing modalities to characterize composition, structure, and performance of the current armamentarium of prosthetic and orthotic polymers prior to and after fabrication. There is need to develop further testing modalities that will mimic the environmental conditions (weathering) of the above materials in clinical service and measure the property changes occurring during that aging.

There is a further need to examine the potential of new polymer materials to serve as the basis of improved prosthetic and orthotic devices. Materials will be chosen for their appropriateness for specific prosthetic and orthotic devices, e.g., differential modulus materials, high modulus polymers and composites, polymers with low temperature of formability, and new interface materials.

Progress—We are currently in the process of: 1) materials acquisition; 2) beginning characterization of armamentarium; and, 3) setting up the weathering machine. There has been progress in the following areas: acquisition of personnel, materials, equipment, specimen preparation, and preliminary data.

Special tooling needs have been addressed. For the Rockwell hardness test, none of the "in house" indenters were of the proper size range, being either too small, thus penetrating the plastic materials completely, or too large, and failing to adequately penetrate. A new indenter of intermediate size is being fabricated. Also, the grinding procedure to obtain small particles for the NMR analysis required cooling the inside chamber of the pulverizer with liquid nitrogen to prevent melting of the materials. Additionally, tooling and templates for the milling of the tensile bars have been assembled.

Preliminary Findings—1) Specimens of Surlyn have been heat-treated to five different temperatures (200, 250, 300, 350, and 400 degrees C) and quenched by either bench-cooling or immersion in an ice-water bath. Subsequently, they will be evaluated for hardness, strength, and elastic modulus. 2) The FTIR spectrum of Surlyn, when referenced to the digitized Sadtler polymer reference library, suggests that it is a 10 percent ethylene/90 percent methacrylic acid copolymer. 3) The NMR spectra of the Surlyn, Subortholen, Durr-Plex, and Uvex have been run but have not yet been compared to the library reference spectra. 4) Specimens of each material have been tested in the Instron tensile testing machine. It appears that due to the broad range of plastic deformation and localized necking, specimen dimensions and Instron operating parameters will have to be modified.

Information and Education Resource Unit

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Purpose—The goal of this project is to establish a database of information related to orthotics and prosthetics for both consumers and those who provide services. This latter group includes health care professionals, third party payers, supporting agencies, and others involved in the rehabilitation process. The center will serve as a link between prosthesis/orthosis users and professionals regarding current research, technological advances, support groups, service, and recreational programs and publications, or other educational materials which can enhance care and quality outcomes. This information will be available via phone or written request as well as printed or electronic copy.

Specific objectives include the establishment of a Consumer Advisory Panel to assist the Center in evaluating current information and resources, organizing and developing needed information, establishing networks with users of prosthetic/orthotic devices, and providing input into the research activities of the Rehabilitation Engineering Program. Based on the initial needs identified, steps will be taken to develop cooperative interaction with various organizations, research and educational institutions, existing databases, clearinghouses, and manufacturers to develop and disseminate appropriate resources. This flow of information will, hopefully, answer consumer concerns, enhance the professionals' ability to provide quality care, and assist engineers and scientists in the posing of important questions. In addition, specific support will be provided to associations currently involved in national and international dissemination of orthotic and prosthetic information.

Progress—To date, the location of the Information Unit and a Project Director have been identified and the computer system is being established. Eight members of the Consumer Advisory Panel, representing a cross section of disabled groups from across the country, have been appointed.

Functional Biomechanical Characterization and Functional Design Specification: Prosthetics and Orthotics

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The design of prosthetics and orthotics components is an empirical process with the evaluation of new design developments based on subjective impressions of the practitioner and user rather than objective performance measurements. New product introductions often claim superior function, making educated prescription a difficult process. This project is to develop methods of characterizing the components and devices on the basis of biomechanical performance and to develop an understanding of the relationship between design characteristics and functional performance. Three areas of investigation are to be mounted: lower-extremity prosthetics, upper-extremity prosthetics, and orthotics.

The lower-extremity prosthetics studies focus on the development and testing of models for the investigation of the effect of compliance of prosthetics components in relation to the energetics of walking; the effect of compliance on the alteration of limb loading; and the control of the prosthesis through control of joint mechanics. The goal is to develop a better understanding of the mechanical characteristics of prosthetics components as it relates to functional mechanics and control of the assembled prosthesis, and to utilize that new knowledge to explore prosthetics design concepts.

Upper-limb prosthetics studies are directed at prehensor slip prevention, and approach and alignment during reaching and grasping. A battery of different materials will be classified, characterized, and evaluated for their possible role in slip prevention. For electrically-powered prehensors, an automatic slip detector is being developed for use in closed-loop control of slip in the prehensor. Approach and alignment investigations include: design of an electrically-powered humeral rotator; computer simulated upper-limb fittings using a database of prosthetics components for the prediction and assessment of prehensor positioning; assessment of reaching and prehensor guidance relative to the mechanics of the hand; and the investigation of dynamic cosmesis during reaching and grasping tasks.

The orthotics section of this project is an investigation of the interface between orthoses and the skeletal structure, particularly as it relates to the interposing soft tissue. The planned activity centers on knee orthoses and their potential capacity for controlling the motion of the bones of the legs. An understanding of the capacity of an orthosis to control bone motion can be helpful as a guide to the design of orthotics hinges and orthotics fixation schemes. The studies are being carried out with attention to the shape, compliance, and amount of coverage of the orthosis in its attachment to the body in order to evaluate how these parameters contribute to the function of orthoses.

Progress—Work to date has been directed at setting up a laboratory for biomechanical measurements. We have a CODA-3 Movement Monitoring Instrument for 3-dimensional static and dynamic position transduction of up to 8 passive markers within a large volume. Modifications are being made to this instrument to bring its performance up to our required specifications. Two AMTI biomechanics platforms have been installed to allow measurement of the 6 components of reaction force at the ground. A raised walkway is being constructed to provide a walking surface level with the force platforms, and is being laminated with a conductive surface for the measurement of phasic activity during gait. Imaging systems are also in place which allow composite images to be made using combined video input and quantitative graphics derived from the CODA and the force platforms. Model developments and subject testing are expected to begin in this next year.

Implications—These studies are expected to provide useful information for the design and evaluation of prosthetics and orthotics systems and components.

Application of Pressure by Elastic Bandages

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Sponsor: *None Listed*

Purpose—Elastic compression bandages are often used: 1) to reduce edema and swelling in trauma patients; 2) in amputation stump management; 3) for increasing the velocity of venous blood flow; and, 4) in controlling the hypertrophic scar formation. However, little information is available on the magnitude and duration of pressures applied by various types of compression bandages that are used clinically. In this study, we are measuring the pressures applied by different types of elastic dressings for various sizes of stockings and for various limb diameters. We also plan to evaluate the decrease in pressure with time due to the stress relaxation of the bandage material.

Methodology—The pressure is being monitored by the use of a miniature flexible pressure transducer with a digital readout. *In vitro* tests are being conducted on cardboard cylinders of various diameters and on a dummy leg. Pressure readings on human volunteers and patients will also be taken.

Preliminary Results/Implications—Preliminary results showed that the pressure applied by different dressings depended on its type, size, and the diameter of stocking. Small changes in the limb diameter did not alter the applied pressure. The initial pressure decreased rapidly with time within the first few hours and it slowly stabilized after 6 to 8 hours. This suggests that for maintaining a constant pressure, the dressings should be changed often. We are continuing this work in order to determine quantitatively the relationship between the applied pressure and the decrease in swelling and edema of lower limb.

B. Lower Limb

1. General

Efficiency of Dynamic Elastic Response Prosthetic Feet

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A517-RA)*

Purpose—The dysvascular and traumatic amputee presents the Veterans Administration with the continuing challenge of effecting rehabilitation and improving function. Prosthetic advances in the last decade have resulted in prosthetic feet designed to better facilitate ambulation. These "stored energy" feet have been touted to replace the solid ankle cushion heel (SACH) foot, which is today's standard device. There is little data available, however, to compare these new dynamic elastic response (DER) prosthetic foot designs with the SACH foot. The objectives of this study are: 1) to compare the efficiency of four DER foot designs with the industry standard, SACH; 2) to define the gait mechanics of these designs; and, 3) to evaluate the relative effectiveness of these prosthetic feet for the dysvascular and traumatic amputees. Twenty subjects (10 traumatic and 10 dysvascular) will be screened and fitted at the Long Beach Veterans Administration STAMP facility and undergo gait lab testing at the Rancho Pathokinesiology Lab to determine gait characteristics and energy consumption. Gait testing will include dynamic EMG, footswitch stride analysis, oxygen consumption, and ground reaction force analysis. Each group of amputees will be compared and correlated for each prosthetic foot design. This study has clinical relevance to the amputee in terms of prosthetic foot selection. Energy conservation and expenditure is critical to the rehabilitation and ultimate functional potential of the amputee. The availability of data for the clinician can provide information concerning function, gait, and biomechanics for each of these new prosthetic feet and will allow for the optimal selection of a prosthetic foot for a given patient's functional needs.

Progress—Phase One involved a pilot study of one dysvascular and one traumatic below-knee amputee, and has supported the feasibility of the project. Muscular activity during walking was increased by all four of the new feet. None of the DER feet greatly reduced the energy cost for the dysvascular patient, while the Carbon Copy II and Seattle feet registered improved efficiency for the traumatic amputee. Advantageous mechanics (increased terminal stance, tibial advancement, and earlier knee flexion) were greater in the traumatic amputee. Inconsistencies between the demand torques and the muscular response were found.

The results implied a difference in patient response and foot dynamics which need to be defined during Phase Two. An above-knee pilot subject suggested an energy cost savings with the Flex-foot. A BK subject suggested that a fluid gait quality contributed by the Flex-foot may place less joint mechanic demands on the below-knee amputee. Further exploration of all these points with more subjects are needed to establish statistical significance and clinical relevance.

Identification of Optimal Amputation Level in Ischemic Limbs

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A419-RA)*

Purpose—The aim of this research project is to characterize perfusion in ischemic lower limbs at rest and during hyperemia induced by temporary arterial occlusion, with the ultimate goal of identifying the level at which an amputation site will heal well while preserving the longest possible stump. Perfusion is evaluated using quantitative Thallium-201 scintigraphy, and a gamma camera linked to a computer. The level of amputation is then chosen on clinical grounds, without knowledge of the test results, and the outcome of the amputation is compared with the level of perfusion assessed by Thallium-201 scintigraphy at the amputation site. Data is also compared to the results of transcutaneous oxygen probe scanning.

Progress—Several phases of information are derived from the study. An initial rapid sequence of images gives a radionuclide angiogram that can be quantitated with time activity curves. Ischemic areas show a delay in time to peak. A sequence of 1-minute images for the first 30 minutes after injection shows the distribution of hyperemia and ischemia in the limb. Time activity curves for this sequence show an early peak and early washout for normally perfused tissue, but a slow accumulation curve in ischemic areas. This tends to support a similar finding by Lassen using Xenon-133. A repeat series of images obtained 3 to 4 hours after injection shows redistribution of Thallium-201 into mildly ischemic areas, with persistent perfusion defects in severely ischemic areas. Comparison of early and late limb profiles, after appropriate correction for isotope decay, expected to show decreased activity in the late profile due to washout, as in cardiac Thallium-201 kinetics, has actually shown no late washout but frequently a slight increase, even in normal areas. The reason for this is a matter for conjecture.

Future Plans—The number of patients studied to date is still too small for good statistical data, but the study is continuing, and includes a group of normal volunteers and a group of diabetic patients without clinical evidence of peripheral vascular disease.

Optimization of Amputee Prosthesis Weight and Weight Distribution

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A349-RA)*

Purpose—Studies of energy expenditure during ambulation performed on above-knee amputees, show these subjects to have a higher expenditure when compared to normal subjects. The objective of this project is to enhance the ambulatory ability of the above-knee amputee by optimizing the prosthesis weight and the distribution of weight within the prosthesis.

Progress—Baseline energy expenditure measurements have been conducted on 6 above-knee amputee subjects. These subjects were tested using their own prostheses and allowed to walk at a self-selected pace. The results were compared to weight variation expenditure results as well as results from normal control subjects and published data on amputee subjects.

Energy expenditure measurements were conducted on a normal control group using ankle weights. Each subject in the control group was measured for energy expenditure under the following conditions: no ankle weights, 1.82 kg unilateral ankle weight, and 1.82 kg bilateral ankle weights. The results from this study will be used as a comparison to the amputee expenditure test results.

Instrumentation to measure limb segment velocities have been completed. Calibration of the instrumentation is currently being performed on normal test subjects. Software programs have been developed to calculate center of mass and the mechanical energy required to move the artificial limb.

A research prosthesis for each test subject has been constructed. Average weight for the prostheses is 2.3 kg. These prostheses were constructed to easily allow the addition of weight and also allow the position of the weight to be varied on the shank or pylon portion of the limb.

Preliminary Results—Comparison of the energy expenditure results between the normal control group and the above-knee amputees confirm previous studies showing the increased energy expenditure for the amputees. Additionally, tests using ankle weights on the normal control group show that distal placement of weights on the limb will cause a significant increase in the energy required to ambulate.

Future Plans/Implications—The energy expenditure tests of the amputee subjects using the research limb will begin shortly. Weight addition and weight placement tests will be performed to the research limbs. Resultant changes in energy expenditure due to weight addition and placement will be used to determine an optimal prosthesis for each patient.

Intraoperative Assessment of Amputation and Decubitus Flap Perfusion

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A463-RA)*

Purpose—The surgical flap is a widely-used and often effective closure following removal of necrotic and gangrenous tissue from a limb. This form of treatment permits salvage of limbs and tissues, thereby preserving more patient function and reducing requirements of extended rehabilitation. However, flaps to cover an amputation site in the presence of peripheral vascular disease will show a failure rate of 20 percent. In the spinal cord injury patient, flaps to cover a pressure sore site will show a 6 to 7 percent failure rate associated with suture separation and necrosis. Prediction of these failures before they occur would permit an alteration of surgical procedures with reduced morbidity and mortality. At the present time, the survival of the flap remains in question for days and sometimes months after surgery.

Our hypothesis is that quantitative measurements taken intraoperatively after the flap has been formed, will assess flap physiologic function and will be predictive of flap survival. We will carry out intraoperative testing in 50 volunteer patients in whom a surgical flap is developed as part of the normal surgical treatment of the patient. The testing will determine the presence or absence of perfusion based upon fluorescein flowmetry, inert hydrogen gas washout, cutaneous perfusion pressure and oximetry. Measurements will be taken after development of the flap and again after the flap has been "tacked" into location with sutures. Flap survival at 7 days after operation will be determined using a set of defined criteria. The sensitivity and specificity of the perfusion tests in predicting flap survival will be calculated. The significance of the results will be evaluated with a binary model.

Since the testing is done intraoperatively after the flap is developed, and also after the flap has been moved into its anticipated location, the results should be of more use in prediction than testing done preoperatively. If intraoperative flap perfusion is not adequately predictive of survival, then it will become clear that other criteria, in addition to perfusion, should be considered by the surgeon in selecting a flap. If the perfusion measurement is predictive of flap survival, it could also be useful in determining the most distal level of amputation compatible with healing.

Evaluation of the Dysvascular Patient

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Sponsor: *VA Rehabilitation Research and Development (Project #A086-4RA)*

Purpose—Individuals with chronic obstructive peripheral vascular disease exhibit tissue ulcerations, gangrene and necrosis. As the disease progresses, tissue necrosis can eventually become extensive, and amputation of the involved limb unavoidable. Similarly, individuals subjected to trauma or large vessel revascularization procedures are at high risk of ischemic tissue damage. In the so-called compartment syndrome, following revascularization surgery, the tissue pressure within the limb increases, causing ischemia. The ischemia causes further elevation in pressure in a progressive cycle leading to irreversible neuromuscular damage. If the ischemia becomes extensive, the entire limb may be compromised, and eventual limb amputation may become necessary. The purpose of this study is to develop the required methodology and instrumentation for determining blood flow and evaluating the functional capacity of the microvasculature within diseased tissues. The ultimate goal is digital and limb salvage, and in those cases where amputation is necessary, a selection of the most distal level consistent with primary wound healing. A surgical flap animal model is also being used to compare small vessel perfusion with tissue viability.

Progress—Instrumentation is being designed to measure: 1) the external viscoelastic properties of the limb as a means for noninvasive assessment of edema and pressure within the limb; 2) blood perfusion of small vessels as determined by the infusion of a fluorescent indicator into the blood; and, 3) the regional tissue perfusion determined from the distribution to body tissues of inhaled hydrogen gas. The viscoelastic measurements are based on a novel approach which does not require limb fixation. A platform resting lightly on the skin provides a reference position. Internal pressure elevation has been found to change the viscoelastic properties of normal healthy tissue toward a more nearly linear elastic behavior, thus permitting an indirect indication of changes in internal pressure.

Fluorometry is a skin perfusion test which uses an intravenous infusion of a dye, but is otherwise noninasive. In the past, it has had limitations in routine clinical use, since the dye can cause severe anaphylactoid reactions in some cases, and a question of consistency of readings occurs with various degrees of skin pigmentation. We have significantly reduced the concern about anaphylactoid reactions through constant dye infusion in such a fashion that the required dose is drastically reduced (0.25 mg/kg). The bolus injection that was previously used is no longer necessary. A fluorescein dye compartmental analysis has shown excellent agreement of a model with experimental data obtained from both the vasculature and subcutaneous tissue. This has given us confidence in a wash-in method for perfusion measurement which reduces measurement time. We have also solved the problem of skin pigmentation as an artifact affecting readings. We have found that we can normalize readings to account for color.

The main advantage of the hydrogen indicator procedure is that the gas is inert and poses little risk in patients, as the gas can be inhaled. The measurements can be made deep in tissues using a small needle probe in contrast to fluorometry which uses surface probes. Measurement of hydrogen gas concentration requires the electrode probe to be in contact with the tissue under investigation. Thus open wounds permit easy assessment of surface tissues and small needle electrodes permit assessment of muscle tissues. The needle electrode is only 0.3 mm in diameter and can be readily inserted through the skin to contact the appropriate tissue. To assess multiple sites simultaneously, additional electrodes would be required and a multiprobe arrangement has been developed. As another alternative to multiple probes, we are examining an increase in probe surface area with fixed probe size.

Preliminary Results/Future Plans—In the surgical flap animal model, a perfusion threshold was able to predict tissue survival immediately following flap formation, with high sensitivity and specificity. For wider applicability, the optical properties of skin tissue with various pigmentation levels are being examined. Since fluorometry involves surface illumination of tissue, pigmentation is a parameter of interest that must be investigated for the wavelengths of light involved. The noninvasive assessment of edema and pressure in the limb is proceeding from a laboratory study to a clinical investigation. The modeling of the viscoelastic tissue response is being improved, by incorporating mechanical changes in traumatized tissues.

Automated Fabrication of Lower Extremity Prosthetic Sockets

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A233-2RA)*

Purpose—The goal of the project is to explore the feasibility of using computer-aided design (CAD) techniques to reduce the hand labor associated with above-knee prostheses.

Progress—The equipment and method for shape and stiffness data collection and the computer algorithms needed for use in computer-aided design of prostheses have been developed. In order to test the equipment and refine the procedures, 10 above-knee amputees were measured for shape, and 20 were measured for stiffness.

The shape testing led to refinement of the data collection procedure so that the movements of the patient did not significantly affect the results. The angular resolution necessary to accurately reproduce the stump shape was determined. A method to collect shape data above the hip joint, which was previously unobtainable, has been devised so that all levels needed for prosthetic fitting are available. Data collection for fitting 10 subjects with prostheses is underway.

The ultrasound stiffness measuring device and data analysis technique have been refined to give consistent and easily measurable results. Testing to determine the differences in stiffness between various areas on the stump is close to completion. The effects of stiffness distribution on the computer finite element model will be determined. Several studies to determine stiffness changes over time, for different disease states, and for different demographic groups, are now possible with this equipment.

Finally, the computer analysis methods have been developed to produce an acceptable prosthesis shape based on both the collected data and the traditionally-used prosthesis brims. The fitting of 10 above-knee amputees using the entire system is underway.

Future Plans—Sockets for an additional 15 amputees will be fabricated to determine what type of patient can be fitted successfully using the computer-aided design technique. Methods for evaluating these prostheses will be investigated in preparation for a more intensive evaluation period.

Publications Resulting from This Research

A Pulsed Doppler Ultrasonic System for Making Noninvasive Measurements of the Mechanical Properties of Soft Tissues. Krouskop T, Vinson S, *J Rehabil Res Dev* 24(2):1-8, 1987.

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Circulatory and Mechanical Response of Skin to Compression Loading

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Sponsor: *VA Rehabilitation Research and Development Service (Project #067-3PA)*

Purpose—This study investigates the relationship between the mechanical properties of skin over bone and skin over soft tissue and the circulatory response to compression loading. The care and treatment of amputations due to diabetes mellitus (DM) and peripheral vascular disease (PVD) are a major responsibility in the patient population served by the Veterans Administration. The restoration of gait through the use of prosthetic limbs requires loading areas of skin which do not normally sustain weightbearing loads, and which may be at risk due to circulatory compromise. Many factors have been associated with skin breakdown, but it is widely accepted that both ischemia and excessive mechanical loading are major contributing variables.

This study encompasses: 1) the relationship between compression loads applied to the surface of the skin and the pressures generated in the subcutaneous tissues over the tibia and over the tibialis anterior muscle compartment; 2) the relationship between applied compression loading and displacement of the skin over bone and skin over soft tissues; and, 3) the relationships between the transcutaneous oxygen pressure ($TcPO_2$) measured at the surface of the skin and the applied pressure and subcutaneous pressure. These relationships are being determined in normal subjects and in patients with DM or PVD.

Progress—The experimental method utilizes Radiometer E5242 $TcPO_2$ sensors to monitor the cutaneous circulation. Studies have shown the relationship between elevated tissue pressures and diminished tissue oxygenation. $TcPO_2$ measurements have shown close correlation with the status of the local circulation and wound healing in the below-knee amputee. $TcPO_2$ measurement reflects the local oxygen delivery in relation to local metabolic consumption. $TcPO_2$ values are diminished in the limbs of patients with PVD.

An Intracath M3LC050 catheter is inserted into the subcutaneous tissue deep to the site of the $TcPO_2$ measurement and connected to a Bell & Howell Type 4-327-0109 physiological pressure transducer to measure the subcutaneous pressure by the infusion technique. Loads are applied directly to the $TcPO_2$ sensor by a portable loading system. Loads are measured with a Sensotec Model 31 load cell, and skin displacement is measured with a Schaevitz Type 500 DCD LVDT. A range of loads is applied sufficient to generate applied pressures from 0 to 125 mmHg.

All data is collected at a sampling frequency of 2 Hz using a Data Translation DT2801A analog-to-digital converter interfaced to an IBM PC/AT computer. Average applied pressure at the skin surface is calculated from the applied loads and the contact area of the $TcPO_2$ sensor. $TcPO_2$ values are plotted against applied pressure and subcutaneous pressure, and regression analysis is used to determine when the $TcPO_2$ reaches zero. At this point all of the oxygen supplied to the skin is consumed by the skin metabolism, leaving no excess to reach the surface. Areas with $TcPO_2$ approaching zero have a reduced ability to heal amputation wounds and, presumably, other insults.

Preliminary Results—Our studies demonstrate that application of external loads causes a reproducible decrease in $TcPO_2$. Skin over bone develops higher subcutaneous pressure and lower values of $TcPO_2$ in response to applied pressure than does skin over soft tissues. For a given applied load, the indentation of skin over bone is much less than that over the soft tissues. The skin over bone shows a significantly more stiff load-deformation relationship than skin over muscle: at applied pressures below 20 mmHg, the response of skin over bone was 2.5 times more stiff; for applied pressures greater than 40 mmHg, the response of skin over bone was 7 times more stiff.

When the leg of a normal subject was elevated

24 cm above the level of the heart, local arterial pressure was lowered by an average of 24 mmHg. Even this mild degree of local arterial hypotension significantly reduced the applied pressure, subcutaneous pressure, and indentation at which the $TcPO_2$ reached zero. This agrees with our results to date for patients with peripheral vascular insufficiency and diminished local arterial pressures who have substantially diminished tolerances for externally applied compression loads and deformations.

Future Plans/Implications—Studies are continuing on the response of patients with PVD and DM to statically applied loads. The response of normal subjects and patients to cyclically applied loads is also being studied. These studies attempt to simulate the loads transferred to an amputee's skin by a prosthetic limb during gait, in which loads vary from zero to maximum in about one second.

Publications Resulting from This Research

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Automated Fabrication of Prostheses and Orthoses

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Projects #A948-PA, #A949-PA, #A950-PA)*

Purpose—The following three integrated pilot projects propose to explore existing systems for the automated fabrication of prostheses and orthoses, the development of shape-sensing software, including rectification rules, and a cooperative field study to evaluate the effectiveness of the two available systems: 1) the UBC CASD below-knee prosthesis; and, 2) the UCL-Roehampton below-knee prosthesis.

This research was considered of sufficient national significance to warrant the combined investigation of three centers. These centers, in Seattle, Chicago, and New York, are affiliated with VA Medical Centers in these cities and with universities (University of Washington, Northwestern University, and New York University) where undergraduate and post-graduate training in prosthetics and orthotics are a formal part of the academic curriculum.

The necessary equipment has arrived, and design and manufacture of below-knee prostheses is actively under way at the Seattle facility. The other two centers plan shortly to enter into the field trial study using similar equipment. This evaluation effort is planned to involve 200 below-knee amputee subjects. Data will be collected in similar form from the three participating centers. The Seattle facility is fitting below-knee amputees only during this phase of the investigation. Rectification rules, together with second-generation software, are anticipated in the relatively near future. Present staff and equipment at Prosthetics Research Study (PRS) allow the processing of information and fitting of 5 CAD-CAM sockets per week.

Automated Fabrication of Prostheses and Orthoses: Development of Prosthetic Shape Comparison and CAD Software (Pilot Project #A948-PA)

Purpose—This pilot study was undertaken to develop computer software and underlying mathematical methods for quantitative analysis of prosthetic socket design. Numerical description of prosthetic design is essential to the Automated Fabrication of Mobility Aids (AFMA) process, and an important means of improving existing designs. Further, because of the sculptural nature of mobility aid design, it was determined that 3-dimensional computer graphics would provide the most informative method of describing mobility aid design. PRS, in conjunction with the Interactive Graphics for Orthopedic Surgery (IGOS) computer graphics research group at the University of Washington, Department of Orthopaedics, has completed the software necessary to carry out the numerical and graphical analysis of 3-dimensional shapes. The software has two components: 1) "Shape Shifter": A program which combines 3-D color display with an alignment algorithm to automatically superimpose, mathematically compare, and then display a multicolored topographical map of the differences between two 3-D objects. (This software is written for a Silicon Graphics minicomputer); and, 2) "AFMap": A program that displays 3-D color contour maps representing the difference between shapes aligned in "Shape Shifter." Computer graphics can be output to a wide variety of readily available computer printers. (This software is written for an Apple Macintosh personal computer.)

Results—The significance of this new technology is that it allows, for the first time, a detailed quantitative analysis of the rectification techniques actually used by skilled prosthetists. Previously, these rectification techniques have not been described, rather they are learned by an apprenticeship process. Thus, each prosthetist develops his own idiosyncratic style by a trial and error process. The 3-dimensional "rectification maps" generated by these new programs enable prosthetists to quickly grasp subtle details of the rectification process. Among other applications, this allows clinical studies of amputees to include rectification technique as a controlled and quantifiable variable.

Future Plans—The current state of our software development is sufficiently advanced to propose a more ambitious program of writing prosthetic/orthotic design software that is more sophisticated than currently available English or Canadian systems.

Automated Fabrication of Prostheses and Orthoses: Evaluation/Demonstration of Roehampton CAD/CAM System (Pilot Project #A949-PA)

Purpose—This pilot study tested the efficacy of an AFMA system for below-knee (B/K) prostheses under development at the Bioengineering Centre of University College, London.

Progress—Through remote use of the computer and manufacturing system in London, Prosthetics Research Study (PRS) has been able to proceed with fitting computer-designed and manufactured B/K prostheses to 12 subjects in Seattle. In the process, the London computer system designed the first prosthetic-check socket blind: that is, without any information about the subject, except for stump shape data and identification. This demonstrated the feasibility of remote manufacturing on the basis of computer data transmitted electronically.

Subsequent modifications to the initial Roehampton designed sockets were requested electronically by PRS prosthetists in Seattle. These modifications accounted for individual subject variations. The experimental protocol involved: 1) Computer digitization of the residual limb of a subject at PRS Seattle; 2) Remote generation in London of a completely computer-designed socket based on the residual limb digitization; 3) Computer-aided manufacturing of socket mold; 4) Return of the socket mold to Seattle via second day air freight; 5) Fabrication of a clear plastic check socket; 6) Clinical evaluation of the fit of the socket; and, 7) Subsequent modifications were requested as necessary via computer satellite link.

Results—The Roehampton system for computer-aided socket design has proven itself as a workable method for B/K socket design and production. The efficiency of the current AFMA-based fitting process was measured in terms of the number of socket iterations necessary to provide a fit satisfactory on clinical exam and for extended use by the amputee: 4 = Maximum number of socket design for successful fitting of prosthesis; 2 = Minimum iterations of socket design for successful fitting of prosthesis; and 2.46 = Average iterations of socket design for successful fitting of prosthesis.

Future Plans/Implications—From PRS experience with AFMA for the B/K prosthesis, it appears that a large-scale experimental demonstration of AFMA technology would be invaluable for its maturation. From the preliminary figures above, the greatest obstacles to a large-scale AFMA demonstration center appear to be mostly organizational in nature. PRS plans to pursue this prospect with the goal of providing the necessary impetus and forum for AFMA to mature to clinical use.

Automated Fabrication of Prostheses and Orthoses: Development of Prosthetic Socket Rectification Rules (Pilot Project #A950-PA)

Purpose—The fitting process of a prosthetic device generates a large amount of detailed data. This includes 1,000-2,000 spatial coordinates to describe the size and shape of the stump and the same number for each socket. This pilot study has sought to exploit these data to predict the final fit from the initial stump description. The predictors of fit have been called socket rectification rules. This work should both help in reducing the number of fits required to achieve a satisfactory fit and help in the development of more sophisticated software to assist in the fitting process.

Results—An experimental protocol has been completed with three subjects that involves collection and computer digitization of permanent plaster models of: 1) The anatomy of the below-knee residual limb of each subject; 2) Plaster casting techniques of three different prosthetists of the same residual limb; and 3) A definitive prosthetic socket worn by the amputee for at least one year. It is hypothesized that analyzing the differences between the residual limb form and the socket form which successfully fits the limb will describe a finite set of rules of socket rectification. Computer software and protocols for digitization of socket rectification patterns using the McDonnel Douglas Polhemus 3-D spatial digitizer has been completed and this portion of the project is finished. The initial step in a comparison of fits is to rotate and translate coordinates of a fit to the same coordinate system as the stump description. This turned out to be a complex procedure that involves the iterative solution of a large system of nonlinear equations. The equations and algorithm have been developed and programmed. Graphical displays of the comparison of the fit and the stump are complete. Digitized shape data files have been transferred to IGOS IRIS computer for analysis.

As described under Pilot Project A948-PA, Macintosh-based software has been developed which shows this data in the form of "rectification maps." We are currently employing this technology as part of our evaluation/demonstration of the Roehampton System, specifically in the comparison of stump shapes with finished CAD/CAM shapes, and the comparison of CAD/CAM shapes with hand-made shapes. Our preliminary observations indicate that even very different shapes can provide a satisfactory fit. Thus, the idea that there is a single "best" shape for a prosthetic socket may be misleading. Instead, there may be a family of shapes that will work for a given patient. The rules that determine whether a given shape is acceptable are as yet unknown. It is anticipated that the results of the current study will assist in finding this answer.

Implications—Demonstrations of our software have evoked intense interest and spirited discussions from practicing prosthetists, who find them uniquely suited to conveying a great deal of information in a compact and convenient form. Rectification maps are a powerful new methodology for prosthetic education, scientific investigation, and prosthetic development. We anticipate that they will find increasing use by our group and other groups.

Clinical and Laboratory Study of Amputation Surgery and Rehabilitation

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A092-4RA)*

Purpose—The VA/Seattle below-knee and Syme's endoskeletal, energy prosthetic system has been developed on the concept of motion and force vectors more physiologically responsive to gravity. The force transfer and movement are incorporated in the design and the prosthetic materials. Component parts are minimized or eliminated. The prosthesis takes advantage of present material technology to include thermoplastics, graphite, composites, synthetic fiber orientation, and cosmesis with a light foam covered by a newly-developed latex skin which can incorporate sleeve suspension where indicated. The limb is designed to be light weight (approximately two-and-a-half pounds for adult sizes), durable, waterproof, and essentially monolithic in construction.

Progress—Individual component parts consist of: 1) The SEATTLE Foot™ or the SEATTLE Lite Foot™; 2) The SEATTLE Ankle™; 3) The PRS prototype intrinsic alignment device; 4) The VA/AFMA computer-designed total contact bearing socket; and, 5) The Cosmetic Prosthetics Skin™. Suspension is elective, depending on the desires of the prosthetist and subject. Currently, sockets are formed by a computer-controlled automated system using the Roehampton CAD-CAM equipment. The entire limb can be designed, assembled, fabricated, aligned, and delivered during the course of one day.

We are in the process of conducting a clinical field trial using 200 below-knee amputees, with services provided by a number of selected VA Medical Centers, and by additional prosthetists, both institutional and in private practice. This limb represents a radical departure from conventional prosthetic management. Automated services are controlled by the prosthetist, computer-assisted. Features involving automation assist the prosthetist, providing him with a "state of the art" tool, comparable to those used in other fields of biological engineering and in industry generally. Prosthetist-amputee relationship is completely individual and personal. Prosthetics skill and experience are the key to success, as is the case with conventional systems.

Results—Additional experience with transcutaneous oxygen and carbon dioxide measurements have established this objective reading as the most practical and accurate test available to the clinician at this time. The use of this technique has spread quite rapidly throughout this country, and in centers overseas. It complements, and in some instances, replaces segmental blood pressure readings when determining limb viability, healing potential, and the anticipated level of amputation in the presence of ischemia. Two members of our investigative team are studying the phosphorus metabolism in the skin using MR spectrometry with specially-designed coils. The information obtained by this technique is coordinated with standardized clinical tests, i.e., $TCPO_2$, to enhance our understanding of the biological phenomena relevant to healing in the presence of diminished blood supply and in particular diabetes. The micro wound skin investigation that has been previously described, has provided sufficient new and original information to justify its publication in several monographs.

Publications Resulting from This Research

Amputations and Prosthetics. Burgess EM, Hittenberger DA. *Orthopaedic Practice,* R. Dee and E. Mango (Eds.) (in press).

Factors Relating to the Sensory Acuity of Limbs with Peripheral Vascular Insufficiency. Matsen FR, Wyss CR, Robertson CL, Love SJ, Hammond MC, Burgess EM, *Surgery* (in press).

Reliability of Transcutaneous Oxygen Tension ($TCP0_2$) Measurements in Elderly Normal Subjects. Olerud J, Pecoraro R, Burgess E, McKnight B, Wyss C, Reiber G, Matsen F, *J Invest Dermatol* (in press).

The Relationship of Transcutaneous PO_2 and Laser Doppler Measurements in a Human Model of Local Arterial Insufficiency. Matsen FA, Wyss CR, Robertson CL, Obert AP, Holloway GA, *Surg Gynecol Obstet* (in press).

Clinical and Laboratory Study of Amputation Surgery and Rehabilitation (Project Extension)

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A092-5RA)*

Purpose—The objective of this study is to continue an ongoing program of clinical and laboratory research into the automated fabrication of mobility aids, lower limb prosthetics, and amputee rehabilitation.

Progress—To enhance the comfort and functional capability of veteran amputees, the ongoing and planned prosthetics research includes the development of a new family of lower limb prostheses, using design and materials technology transferred from industry and related, non-prosthetic disciplines. The state of R&D for these prostheses is well along in its development. The SEATTLE FOOT has now been fitted commercially to more than 20,000 lower limb amputees, many of whom are veterans. An improved, more versatile, and lighter unit is being developed primarily by the manufacturers. The Prosthetics Research Study Center (PRSC) will contribute research input to this new unit as it combines with other elements of the lower limb prosthetic system.

The endoskeletal Ankle/Shank component continues to be evaluated at selected VA Medical Centers under the direction of VA RR&D. Input from this national evaluation will allow stabilization of design and materials. Commercialization should take place within the next 9 to 12 months.

An intrinsic alignment system of compatible, composite materials is undergoing in-house testing and will also be available for national evaluation in the next few months. This device will be incorporated as a permanent part of the VA/Seattle prosthetic system. The PRSC, under a parallel but separate project, is now fabricating CAD/CAM sockets by an automated system. These sockets are also undergoing in-house clinical trials. They will become an intrinsic part of the same VA/Seattle prosthetic system.

Cosmesis research has progressed to the point of development and use of computerized, mirror-image limb molds for endoskeletal B/K systems. Spray-on surface cosmesis has also been developed, and is undergoing continuing investigation. Our cosmesis development includes a removable cover, light, tough, with tear and perforation resistance, stain-resistant, easy-surface cleansing. The superior extension of the cosmetic cover above the brim of the B/K socket provides suspension capabilities using the sleeve principle. This research is also being coordinated with that of the Franklin Institute, Philadelphia, PA, who are in collaboration with us and, with VA RR&D support, is addressing the problem of lower limb cosmesis. It is anticipated that these items will be available for commercialization during the 1989 fiscal year.

The below-knee energy-storing VA/Seattle prosthetic system is compatible with any one of a number of existing knee mechanisms for use with a knee disarticulation, A/K, and hip disarticulation prostheses. Research, development, and evaluation will be extended to higher levels as well as the Syme level during the next two years.

Concerning the effectiveness of present surgical management, including post-operative evaluation, level selection, surgery, and immediate post-surgical care to stable wound healing, the joint effort by the Limb Viability Team and the Surgical Team for Amputations, Mobility, Prosthetics & Orthotics (STAMP) Service at VAMC Seattle will expedite this study, thus increasing our statistical experience using segmental blood pressure. $TCPO_2$ measurements, radioactive wash-out, skin temperature and laser Doppler flowmetry, fluorescein flowmetry, and nuclear magnetic resonance spectrometry. Inert gas diffusion through the skin as a means of evaluating skin viability is being accomplished using carbon dioxide electrodes. Other STAMP Centers are also cooperating in this additional limb viability test.

PRSC is collaborating with research units in the endocrine and medical sections at VAMC Seattle in studying the effects of certain biological growth factors and wound healing accelerators in treating diabetic and ischemic ulcers of the lower limbs. We intend to further capitalize on the widespread research and interest in biological growth factors as related to tissue repair.

Energy-Storing Prosthetic Feet

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Sponsor: *Commonwealth Department of Veterans' Affairs, Australia*

Purpose—Our purpose was to test prosthetic feet by comparing their mechanical capabilities for storage and release of energy.

Methodology—Seven types of prosthetic feet were tested by examining their force-deflexion characteristics, under certain given conditions. It was assumed that all prosthetic feet were critically damped and that their natural frequency was such that the stored energy was returned within 0.1 of a second, or as soon as the foot was unloaded. It was also assumed that the energy-storing material maintained, throughout loading, a constant cross sectional area. The following types of prosthetic feet were tested: the Carbon Copy, the Dynamik-Fuss, the Greissinger, the SACH no toes (Kingsley), the SACH with toes (Kingsley), the SEATTLE, and the Sten. All feet were size 27, left. The Carbon Copy was a "Regular" and the "SEATTLE" was a 80 kg foot.

Results—Both the SEATTLE and the Greissinger have very straight force-deflexion slopes, therefore they will always be closer to the ideal energy-storing potential. The Greissinger and the Sten have very poor energy-return efficiency. The SEATTLE, Dynamik-Fuss, Carbon Copy and Greissinger fall within an acceptable walking range. The SEATTLE was easily the most suitable foot for the patient conditions chosen, both in energy-storing potential and energy-returns efficiency.

CAD/CAM for Leg Prostheses

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is the application of new materials and production methods for sockets and cosmetic provisions for leg prostheses. This involves: 1) inventory of new materials and production techniques for the production of sockets; 2) inventory and evaluation of techniques for inside measurement of sockets; 3) inventory and evaluation of measurement and production techniques for the sake of cosmetic finishing of prostheses; and, 4) testing of these measurement and production techniques under production circumstances.

The MERU software packages of STI, Vancouver, Canada are being used in this project.

Results—An up-to-date application of processing technology for synthetics will soon be made suitable for the production of higher-quality prosthesis sockets. A computer-aided design and computer-aided manufacturing (CAD/CAM) system for cosmesis has proven feasible.

This project was conducted with the cooperation of St. Maartens Clinic, Nijmegen.

Flat Spring Foot Prosthesis

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Sponsor: *National Health Research and Development Programme, War Amputees of Canada*

Purpose—Unilateral below-knee child amputees experience asymmetry in hip angle and push-off duration using the SACH foot. Improved function has been obtained with the Seattle Foot and Flex Foot prostheses by use of a flat spring with a curvature at the ankle. An analysis employing this concept has been made where the deflection of the spring is optimized throughout stance. An arched cantilever beam model has been developed to determine the spring deflection throughout foot-flat to toe-off in order to optimize the spring design.

Methodology—Using the kinematic results of a gait study of a normal adolescent, the sagittal deflection of a foot prosthesis, having a single axis of flexion in the metatarsal region, was simulated kinematically at a CAD graphic work-station. The simulated positions of the prosthesis during the stance phase were then combined with the sagittal forces and moments at the knee obtained from the gait study, to predict the ground reactions that would occur on the prosthesis. These were then used as input to the arched cantilever beam model, where Castigliano's method for beam deflection was applied to the curved spring, to determine its deflection throughout foot-flat to toe-off. The angle and radius of curvature, thickness, and width of the spring were optimized using the nonlinear SIMPLEX method to match the deflection of the free end of the spring determined by Castigliano's method and that of the simply-hinged forefoot simulated graphically. The root mean square (RMS) value of the differences between the deflections of the beam and graphic models summed over time was used as the objective function. Constraints in the optimization were based on tolerable dimensions of the foot and the allowable stress in the spring.

Results—The optimization was performed for Torlon and Delrin where the RMS values for foot-flat to toe-off, and for heel-off were 16 mm and 21 mm, respectively, and 18 mm and 23 mm, respectively. The ability to minimize these values is partly limited by the mechanical properties of the material and investigation of other materials may be required if these RMS values are to be reduced.

The Flat Spring Foot (FSF) prosthesis was then fabricated and fitted to a 14-year-old unilateral BK amputee. Even though the subject had the FSF prosthesis only for a period of two days, he preferred it to his Seattle Foot. He felt that spring-like action of the heel contributed to a better push-off. A gait study was performed, and preliminary results show a greater symmetry in the impulse values when the FSF prosthesis is used, as compared to the Seattle Foot. Although it is too early to make definitive comparisons, it appears that our prosthesis compares well to the Seattle Foot. In addition, it has the advantage of being easily adapted to children.

Publications Resulting from This Research

Preliminary Evaluation of an Optimally Designed Flat-Spring Foot Prosthesis for Children. Allard P, Kofman J, Labelle H, Levesque C, Duhaime M, *Orthopädie Technik* 39:261-268, 1988.

B. Lower Limb

2. Below-Knee

National Program for Automated Fabrication of Mobility Aids: Eastern Region

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A514-DA)*

Purpose—The objective of this project is to obtain quantitative clinical data for use in developing an improved computer-aided design and computer-aided manufacturing (CAD/CAM) system for prostheses for below-knee (BK) amputees.

Methodology—To achieve this objective, the following research plan is proposed. Clinical fittings of approximately 30 B/K amputees with CASD/CAM sockets and prostheses will be performed using the computer-aided socket design and computer-aided manufacturing (CASD/CAM) system developed by the Bioengineering Centre at the University College, London, England. This work will be performed in collaboration with the Prosthetics Research Study (PRS) in Seattle, WA and the Prosthetics Research laboratory at Northwestern University (NU-PRL) in Chicago, IL. These two centers and their affiliates will fit an additional 160 to 170 B/K amputees with CASD/CAM sockets and prostheses to provide a program database with a total sample population of approximately 200 B/K amputees.

Information regarding the general physical condition, health, and the type, range, and extent of prosthesis use will be compiled for each subject participating in the project. In addition, measurements of the physiological, biomechanical, and prosthetics characteristics implicitly affecting the type, magnitude, and distribution of forces at the socket/stump interface will be made for each subject. Plaster of Paris wrap casts of the subjects' stumps will be taken, and the resulting cast contours digitized and input into the CASD computer. Using this data, CASD/CAM sockets and prostheses will be made and tested on each subject. The subjects will be followed over a one-year period to evaluate the fit and performance of their CASD/CAM sockets and prostheses.

During the final quarter, statistical distributions of, and correlations among, the subjects' measured physiological, biomechanical, and prosthetics characteristics will be calculated and tested for trends. These results will be used for future development of improved stump characterization techniques, to enhance socket design principles, and to expand knowledge of prosthetic socket/stump fitting mechanics. In addition, correlations between the success or failure, and ease or difficulty of fit (number of check sockets required), and the physiological, biomechanical, and prosthetics characteristics of the experimental subjects will be performed. These results will be tested for trends to identify categories and characteristics of patients that can be successfully and easily fit using the UCL CASD/CAM system. Finally, the program results will be used to formulate recommendations to the VA Rehabilitation Research and Development Service (VA RR&DS) as to the most efficacious, expedient, and cost-effective plan for developing an improved VA Prosthetics CAD/CAM system.

National Program for Automated Fabrication of Mobility Aids: Central Region

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A521-DA)*

Purpose—We propose to participate in a national program with the Prosthetics Research Study in Seattle, and the VAMC New York, in a cooperative clinical study of computer-aided socket design (CASD) and computer-aided manufacturing (CAM) of below-knee prostheses. We plan to fit approximately 30 amputees per year, for two years, as part of a program that will involve the fitting of over 200 amputees through the computer-aided approach. The equipment and techniques to be used will be basically as developed at the Bioengineering Centre of the University College London. This is a development proposal because the approach is to determine the efficacy of the present equipment and methods, and to uncover possibilities for its refinement and improvement. The results should have a salutary influence on this newly-emerging area of limb prosthetics.

Traditional methods of prosthesis design, fabrication and fitting are laborious and time-consuming for the prosthetist. Recently, there has been considerable interest in applying modern technological methodologies to the automation of these traditionally manual tasks. This automation has been termed CAD/CAM, which is the often-used industrial acronym for computer-aided design and computer-aided manufacture. Industrial CAD has, until very recently, been nothing more than a computer-facilitated drafting process. The designer traded pencil and scale for a graphic computer terminal; however, the basic process of design remained unchanged. This is somewhat the state of affairs with CAD/CAM techniques in prosthetics, and the systems we will be using in the clinical study are primarily involved with methods. The computerized tools are different and helpful, but the design concepts are basically unchanged.

This is the first step in moving into the CAD/CAM arena. In the newly-emerging applications of computer-aided engineering (CAE), several aspects of the design process are automated, in addition to drafting. As a result, the implementation of CAD today can range from computer-assisted drafting to computer-automated design. The field is moving in this direction in prosthetics, and the proposed study will assist developers move toward systems that assist in the engineering of prostheses, as well as carrying out existing procedures more efficiently and accurately.

Computer-aided socket design (CASD) and computer-aided manufacturing (CAM) of below-knee prostheses have been introduced in a preliminary way to clinical practice, primarily in Canada and the U.K. Research and development work on this topic is now intense in many countries, including the U.S.A., and the VA Rehabilitation Research and Development Service is funding several R&D projects in this area. Consequently, the time is right for a controlled study of this new approach to prosthesis design and fabrication.

There is a need to examine and evaluate the procedures and equipment that are now available for clinical trials. It is important that this initial work be done in research centers. In this way, *controlled* testing and evaluation of results can be carried out on CASD/CAM systems by knowledgeable and objective groups before there is wide-scale clinical introduction of these methods in the United States. Also, the research work of R&D laboratories engaged in work on CAD/CAM can benefit from the clinical experience of using existing CAD/CAM technologies and methods.

The controlled testing and evaluation at different centers across the country will establish the efficacy of the approach, establish norms against which future results can be compared, help refine the present systems and approaches, and facilitate the orderly transition of these new methods into clinical reality and into the service of veterans who are amputees. The clinical experiences with CASD/CAM in the R&D laboratories will enhance the research and development work already going on in these laboratories by providing the researchers with direct clinical experiences that will influence and modulate their own R&D efforts in practical ways.

National Program for Automated Fabrication of Mobility Aids: Western Region

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Sponsor: *VA Rehabilitation Research and Development Service (Project #504-DA)*

Purpose—The purpose of this research is to continue and extend development and evaluation of automated fabrication of mobility aids (AFMA) systems for lower-limb prostheses.

Methodology—Three VARR&D national centers are collaboratively involved in this program: Prosthetics Research Study in Seattle, Northwestern University Prosthetics Research Laboratory (NU-PRL) in Chicago, and New York University Medical Center, Rush Institute of Rehabilitation Medicine (NYUMC-RIRM) in New York. Reinforcement is increased in scope by close cooperation with the University of London/Roehampton Bioengineering Unit (UL/RBU), and the NASA Research Center, Langley, VA. The requested research proposes to test and evaluate clinically, the now-functional technique. With an increasing clinical experience, and in collaboration with our investigators at the other sites listed above, we believe that over the next two fiscal years, this radical change in prosthetic technology can provide a state-of-the-art prosthetic fabrication tool that can extend the scope, efficiency, improved function, and cost benefits that appear within reach.

At present, the Seattle Center has the capability of duplicating the London experience. CAD/CAM sockets are now being fabricated and fitted to test veteran subjects using equipment provided on a loan basis from the UL/RBU. PRS proposes to purchase the second generation of this equipment, and continue in-house and outreach prosthetic fittings, using automated technology and the London prosthetic socket design software.

This program is considered a development effort. Coincidence research into improved systems of shape-sensing, and the development of second- and third-generation software, would be expected to progressively increase the effectiveness of the AFMA system. The implications of this research and development are far-reaching. The goal is to greatly increase the availability of prosthetic appliances functionally equal, or superior to, present labor-intensive devices. If successful, the AFMA system should not only bring prosthetics, orthotics, and the fabrication of orthopedic devices such as footwear, into the main stream of present-day technology, it should even more effectively address the overwhelming and unsatisfied demands of the Third World societies.

The program as outlined is ambitious. By the beginning of the 1989 fiscal year, clinical trials of the Roehampton System will have included a larger number of subjects than has now been fitted and studied worldwide. As development and evaluation proceed according to scheduled plans, technology transfer to commercialization and general availability is certainly no more than a year away. VA leadership in this critical, high-priority effort reflects dedication to improving the quality of life of the veteran handicapped population with an outreach extending to the general population of this country and throughout the world.

CAD/CAM of Below-Knee Prosthetics: Socket-Limb Mechanics

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Sponsor: *VA Rehabilitation Research and Development Service (Project A317-2RA, Part 1)*

Purpose—Structural modeling of the limb/prosthesis system is seen as an aid to understanding the implications of socket designs from a biomechanical viewpoint, with possible application to the func tional evaluation of prosthetic components. Effective use of modeling requires a methodical approach with continued validation of the methods. At Northwestern, we are conducting investigations on the use of finite-element analysis in the design of below-knee (B/K) sockets. Our approach to verifying model validity has centered on attempts to match experimentally-measured interface pressures with interface pressures predicted via our three-dimensional finite-element analyses.

If a workable model of the B/K limb/socket system were achieved, it would become a powerful design and manufacturing tool. It could be used to predict the pressures generated by an expert prosthetists' rectification displacement field. If the rectified shape were placed over the surface of the undistorted geometry of the limb, a pressure pattern would result. This pattern would be the pressure which has been applied to the residual limb by the prosthetists' shape modifications. This would provide insight into the force transfer patterns provided by the prosthetists' modifications to shape. Similarly, a desired pressure pattern could be input into a finite-element model and solved for displacements. This new shape could be considered the rectified shape of the socket and created using computer aided manufacturing (CAM) techniques.

Progress—Results of linear modeling had correctly predicted the range of experimental pressure measurements (0–12 N/cm^2). However, the distribution of the predicted to measured pressures did not match well. It was felt from this initial work that even though the ranges of pressure matched for the predicted and experimental results, the lack of one-to-one correspondence indicated a need for refinement of both the modeling and experimental techniques. The initial analysis used linear, small-strain elastic assumptions. The inconclusive results indicate that these assumptions may be too limiting, considering the deformation range and nonlinear characteristics of soft tissue. Work has begun on nonlinear modeling of the limb/socket system.

As a first step, the original two models were converted to a new finite element code with nonlinear capabilities and reanalyzed as simple linear small-strain problems. The only alterations in the modeling was to represent the soft liner as a linear elastic foundation around the appropriate surface of the limb and to place an elastic foundation on the proximal tissue surface to represent the effects of the upper unmodeled thigh. Results were similar to previous results, but with pressure ranges of 0–6 N/cm^2.

A smaller generic "check" model of bone and tissue was created to determine the effects of varying material and geometric representations of soft tissue. In this analysis, an incompressible isoparametric element type was chosen. This element differs from the standard 8-noded linear isoparametric element in that it possesses an internal ninth node which contains a Lagrange multiplier. The analysis also considered the material to be an elastomer (Mooney-Rivlin model). The results indicated that while the linear versus nonlinear results are similar, they differ enough to account for the insufficiencies of our earlier model verification attempts. Conversion of the initial linear models to large strain incompressible models will be the next step in the work.

Work is also progressing on characterization of tissue material properties. A barograph device is being designed to characterize *in vitro* tissue properties. Preliminary experiments on *in vivo* tissue have been conducted and indicate that tissue behaves in a repeatable fashion without first having to be preconditioned. A finite element model of these experiments is under development to aid in quantifying material properties of tissue.

Publications Resulting from This Research

Prediction of Pressure at the Below-Knee Socket Interface by Finite Element Analysis. Steege JW, Schnur DS, Childress DS, *Biomechanics of Normal and Prosthetic Gait Symposium of the 1987 ASME Winter Annual Meeting*, BED (4), DSC (7):39-44, Boston, MA, 1987.

CAD/CAM of Below-Knee Prosthetics: Anatomically-Based A Priori Alignment Prescription Studies

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A317-2RA, Part 2)*

Purpose—Below-knee prosthesis alignment is an iterative procedure based on heuristic rules applied by a prosthetist in response to visual evaluation of an amputee's gait. Prosthetists can become quite expert at alignment, although the particular alignment settled on is known to vary, based on the particular prosthetist doing the alignment. The rules used by the prosthetist suggest that alignment changes are made chiefly in response to undesirable limb loading, yet the clues used in the application of the rules are observed gait abnormalities, rather than loading abnormalities. This indirect approach to alignment—using kinematic observations to infer the kinetics of gait—may be responsible for the poor overall understanding and variability of below-knee prosthesis alignment. In contrast, the similar task of aligning a total condylar knee prosthesis relies on the less subjective use of jigs designed specifically around the biomechanics of lower limb support. Since the orthopedic surgeon does not have the luxury of making iterative changes to alignment, he has been forced into developing a scheme for effective *a priori* alignment. The goal of this project is to utilize gait analysis techniques in the study of B/K prosthesis alignment; to investigate the fundamental effects of alignment on the loading of the limb; and to identify a positional alignment prescription that does not require the use of trial and error adjustments. A key aspect of this study is that all analyses are to take part in a rigidly defined axis system defined by the anatomic geometry of the lower limb. The loading (mechanical) axes of the bones and the kinematically defined geometry of the joints allow meaningful axis systems to be defined in the tibia, the femur, and the pelvis. In addition, by defining the axis origin for the prosthetic foot as being located at the posterior aspect at the base of the heel, we will decouple the effects of alignment position and alignment orientation and better identify the relationship of each to limb loading.

Progress—We are in the process of assembling a gait analysis laboratory to be used in these studies. Alterations are being made to a CODA-3 Movement Monitoring Instrument to enable precise position transduction of global cartesian coordinates of up to 8 passive markers with associated software, allowing local axis systems to be established and tracked, relative to either the global axis system or another local axis system. Two AMTI biomechanics platforms will give the 6 components of reaction force at the ground. A raised walkway is being constructed to provide a level walking surface and will be laminated with a conductive surface for measuring the phasic activity of gait, the circuitry for which is currently being designed and tested. Work is also proceeding on development of the experimental protocol; the software interface for experimental setup, data collection and data analysis; and a jigging system for accurate determination of pelvic motion.

Implications—The capability of specifying the proper positional relationship of the foot and the socket before beginning fabrication of the prosthesis eliminates the need for adjustable alignment hardware. This is of special interest in the application of computer-aided design/computer-aided manufacture of prostheses, where an entire artificial leg might be fabricated as a single unitized piece without the provision for any additional hardware for either structural or alignment purposes.

Publications Resulting from This Research

Anatomically-Based Gait Analysis for Below-Knee Prosthesis Alignment: An Experimental Method. Van Vorhis RL, Rovick JS, *Biomechanics of Normal and Prosthetic Gait Symposium, ASME Winter Annual Meeting,* BED(4), DSC(7):121-126, Boston, MA, 1987.

Further Development of the ISNY Below-Knee Flexible Socket System

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Purpose—For many years the "suction" concept has been utilized with reasonable success on selected above-knee amputees. There has been, however, a corresponding lack of success with below-knee amputations, because of the bony residua which permit channels to form between the stumps and the socket walls through which air can pass. In addition, most below-knee amputees wear woven (porous) "stump socks," making it impossible to maintain a vacuum.

Due to gravitational and other forces, there is always the tendency for prosthetic devices to separate from the residua, especially during the swing phase of gait. A variety of belts, straps, cuffs, and socket configurations are routinely used to retain prostheses on the residuum. However, none of these provide the instantaneous strong retentive forces available through differential (hypobaric) air pressure.

Progress—The present development involves the incorporation of an air seal between the below-knee stump and socket liner or socket just below the tibial plateau, along with a distally located one-way air valve. Since the effectiveness of the seal is directly dependent on the closeness of fit of the prosthetic socket, it works best as an extension of the ISNY flexible socket design which provides a very intimate fit with the residuum, especially during periods of muscle activity and movement. The seal functions independently of the socket configuration being used (PTB, SC, TSB, etc.) and to a point, the characteristics and dimensions of the seal are alterable to function with looser-fitting conventional sockets.

Methodology—The process of developing the necessary experimental evidence regarding the practicality of the hypobaric system proceeded as follows: initially, a rubber model of a typical below-knee stump was fabricated to simulate the shape and consistency of the human residuum. Socket inserts of sheet polyethylene (ISNY) and liners of porous polyethylene (PELITE) were fabricated and fitted to the model in conjunction with the air seal and valve. Tests showed that significant retention due to differential air pressure resulted: the data indicating that 50 pounds of force (the upper-limit of the test instrumentation) failed to separate the inserts or liners from the model.

Encouraged by these results, seven below-knee amputees, wearing PTB and SC ISNY sockets were recruited. Of this group, five have been successfully fitted, while the other two are still in process. Subsequently, six wearers of conventional Pelite-lined PTB and SC sockets were recruited, resulting in two successful fittings and one failure, very likely due to very excessive, soft, redundant, posterior tissue. Fitting efforts continue for the remaining three subjects (although two of the subjects, with very tapered residua, present retention problems).

Results—Of those amputees fitted successfully, none have experienced any difficulties in retaining the socket on the residuum without straps or condylar supports. The advantages of the system are well summarized by their comments: "no pistoning, lightness, improved retention, increased control and comfort."

Implications—These clinical studies have helped formulate and refine the technical changes in prosthetic fitting and fabrication techniques required for the successful application of hypobaric retention. Experience to date suggests that the widespread, successful use of this hypobaric suspension technique is a viable goal for many below-knee patients.

Syme Ankle Prosthesis: A Pilot Study

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Sponsor: *Rehabilitation R&D Unit, VA Medical Center (Atlanta) Core Funds*

Purpose—The purpose is to design and build a prosthetic ankle joint for the use of Syme amputees. In a Syme amputation, only the foot is removed, leaving the tibia and fibula intact. All the tendons are cut, however, leaving the natural joint ineffective.

The primary design objective is to simulate the range of motion and the energy absorption of a natural joint. This is complicated by the fact that the center of rotation of the joint lies in the lower shank itself. Thus, the center of a prosthetic ankle joint cannot be produced by a simple mechanical bearing and shaft arrangement. Other design objectives include simulation of the action of the lower shank and foot muscles and tendons, as well as lateral stability and vertical shock absorption.

Progress—The progress to date consists of: analysis of the natural ankle joint and the needs of a Syme amputee; a design to meet these needs; strain energy calculations; strength of materials analysis; spring design; and machining and assembly considerations.

Articles were researched to attain some quantitative feel for the forces, moments and strain energy which exist in a natural ankle and foot. The basic design concept came from Danny Holtzer, who suggested the use of a curved sliding bar in a curved slot, to create a pivot around a center without having to invade that actual center area. The connection to the amputee's stump must be made by a standard metric threaded fitting commonly used in prosthetics. This must be positioned as low as possible to allow natural leg height. Improvements were made to avoid the problem of binding by using miniature needle bearings at four points on the previously sliding bar. Delrin plastic resin was chosen to build the curved slide or track and the artificial foot arches. This was due to Delrin's good resilience and compressive strength. Calculations were done to estimate the strain energy which the Delrin arches of the artificial foot would absorb and then rebound on toe-off. This led to the final dimensions of the arches. Two arches were used to better simulate the flexibility and stability of the natural foot. A strong alloy of aluminum was chosen for the upper bar or shank. Clearances were calculated to allow the rolling mechanism to operate smoothly, but without excessive free play. A titanium shaft would be press-fit into the aluminum to mount the needle bearings. The sizes of the shaft and bearings were defined by a worst-case weight, moment and force distribution, and as a safety factor. A machining and construction plan was laid out and tooling was purchased. Jigs or fixtures were built to hold the parts precisely while machining was done. Material to build a small number of prototypes was purchased. Actual construction is now underway.

Evaluation of a Software Package for Computer-Aided Socket Design

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project was to evaluate a software package developed at the University of British Columbia, Vancouver, Canada, that, when aided by the computer, designed and produced prosthesis sockets for people with lower leg amputations.

Results—The final conclusion of the report is that with a maximum of three sockets per patient, 80 percent of the examined patients (24 patients in all were checked) could be provided with a good prosthesis.

This project was conducted in cooperation with the Institute for Rehabilitation Muiderpoort, Amsterdam; St. Maartens Clinic, Nijmegen; and, Westpark Rehabilitation Technique, Helmond.

Clinical Testing of a Bicycle Attachment for Conditioning of Below-Knee Amputees in the Early Postoperative Stage

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Purpose—We have identified the need for a device that would permit below-knee amputees to exercise large muscle groups of both lower extremities without interfering with wound healing. The use of upper extremity and one-legged exercises has been attempted to improve conditioning in the amputee, with limited results. Upper extremity exercises use muscle groups which fatigue easily and increase blood pressure. Also, there has been proven to be no transferability of training from upper extremity exercise to lower extremity exercise, particularly ambulation. One-legged exercises, on the other hand, are difficult to perform by the patient and would not provide training of the amputated limb. Ambulation used to improve cardiopulmonary endurance is well known. Unfortunately, for this population, in the early postamputation period, the condition of the residual limb will generally prevent ambulation even with an immediate postoperative pylon. A device that permits the attachment of the below-knee residual limb to a stationary bicycle has been designed and fabricated.

Progress—Clinical testing of the device in a group of 12 unilateral below-knee amputees and 2 bilateral below-knee amputees in the early postoperative period has been completed. Good adjustability, patient tolerance, and acceptance to the device was noticed. There was no evidence of skin irritation or reports of pain in any of the subjects. The subjects were able to pedal up to an average of 18 minutes (13 to 20 minutes).

Preliminary Results—No residual limb or systemic complications were encountered during this limited testing. Clinical evidence of cardiac and respiratory responses necessary for conditioning were present. Minor design modifications to the device were performed to accommodate the bilateral below-knee amputees. These subjects appeared to gain the most physiological and psychological benefit from training with the device.

Future Plans/Implications—A comprehensive clinical trial study to assess metabolic, cardiovascular, and musculoskeletal effects of the device in unilateral and bilateral below-knee amputees is in progress. Future applications of this device are in cardiovascular exercise testing and sports for below-knee amputees. The device has a patent pending.

Investigation of the Optimal Load-Bearing Characteristics of Patellar Tendon Bearing (PTB) Prostheses

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Sponsor: *National Science Foundation*

Purpose—The long term goal of the research team is to automate the construction of the lower limb prostheses using Computer Integrated Manufacturing (CIM) techniques. To accomplish this, our understanding of the amputee-prosthesis system must be broadened. This ongoing project is specifically looking at load transmission through the stump-socket interface. This information will be combined with the results of two other investigations; one looking at the dynamic and structural characteristics of the prosthesis as a whole, and the other looking at the amputee and his/her compensatory activities due to physiological attitudes or physiological limitations.

These studies will provide us with the information necessary to develop a method for automated design of customized prostheses. This method will be integrated into a CIM process. The ultimate result of this project is expected to lead to an improvement in the quality of prosthetic care delivery, based on quantitative and objective measures.

Methodology—Instrumented prostheses are manufactured for each subject. Interfacial forces are measured at the patellar tendon, as well as pressures at the distal end of the stump. The socket geometry is altered in the patellar tendon and the stump-end regions. These forces and pressures are collected simultaneously with ground reaction forces and kinematic data.

Progress—Fourteen below-knee amputees (11 men, 3 women; ages 28 to 67) were fitted with the experimental prostheses, and several more subjects are currently being sought. Data has been collected on 10 of the subjects (4 could not complete the protocol), with information gathered on a variety of socket geometries.

Results—The following is a summary of results for the past year: 1) The original design of the instrumented prosthesis has been modified extensively to decrease weight and improve accuracy; 2) A mathematical model of the stump-socket interface is being developed for a better understanding of the interdependency of load bearing regions of the residual limb; 3) Preliminary results have led to an investigation of the cause of instability at the stump socket interface, and its probable causes. This information was presented at the 1988 East Coast Clinical Gait Analysis Conference; and, 4) Other experimental results have been analyzed and reported.

Publications Resulting from This Research

Structural Synthesis of Lower Limb Prostheses for Optimal Gait Performance. Seliktar R, *Proceedings of the 13th Northeast Bioengineering Conference*, Philadelphia, PA, 237-240, 1987.

Toward Automation of the Manufacturing of Lower Limb Prosthesis. Seliktar R, *Proceedings of the Special Congress of the International Society for Prosthetics and Orthotics*, Israel, 1987.

Gait Performance Following Skeletal Modification or Lower Limb Amputation. Seliktar R, Mizrahi J, Vachranukunkiet T, Besser M, Kuenzig D, *IEEE Engineering in Medicine and Biology Society 10th Annual Conference*, New Orleans, 1988.

Human Performance with Prosthetic Devices and Surgically Modified Skeletal Elements. Seliktar R, Mizrahi J, Vachranukunkiet T, Besser M, Kuenzig D, *Automedica* (accepted for publication).

B. Lower Limb

3. Above-Knee

Geriatric Prosthetics: Design and Development of an Improved Above-Knee Socket

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Purpose—The objective of this project is to investigate and quantitatively determine the prosthetics requirements of geriatric above-knee (A/K) amputees, and develop quantitative design procedures for prosthetic sockets for these amputees.

Progress—Work has continued on measuring the physiological, biomechanical, and prosthetics parameters of geriatric and non-geriatric A/K amputees and control subjects. Seventy-eight subjects (43 amputees and 35 control subjects) have been tested to date. Measurements from these subjects are being compiled in a computerized database. Statistical trends in the data obtained from the subjects to date continue to be evidenced.

Work has continued on A/K socket design derived from uniform cross-sectional force/tissue displacement (UF/TD) measurements. Sockets for 4 additional subjects have been designed, fabricated, and incorporated in prostheses for clinical evaluation and testing. The UF/TD sockets fitted to date have all been judged comfortable and stable anteroposteriorly, mediolaterally, and rotationally. Follow-up of the subjects who are field-testing experimental prostheses with UF/TD sockets is continuing.

Measurements of amputee localized tissue circulation and net stump circulation have been obtained with and without the subject's experimental prosthesis with UF/TD socket, and his/her prosthesis with conventional quadrilateral socket. Investigations of stump skin capillary perfusion as a function of localized loading were performed using a laser Doppler system. However, because the laser Doppler system fails to provide an absolute measure of local circulation, these measurements have been discontinued until other instrumentation can be found. Stump tissue net circulation is being measured using an Advanced Technology Laboratories Ultramark dual mode ultrasonic monitor. Subjects are stressed under an arduous walking regimen without their prostheses, using crutches, and after cardiovascular and muscular recovery, with their experimental prostheses with UF/TD sockets, and then with their prostheses with conventional quadrilateral sockets. Before and immediately after each test, sonograms are obtained and used to position and focus the ultrasonic transducer beam in the center of the femoral artery at perineal level. Pulse rate, mean flow velocity, pulsatile acceleration, systolic and diastolic amplitude, and unit flow volume are then measured, using the Doppler mode of the system. Results are being compiled in a database for analysis.

Development of an instrumentation system for measurement of static and dynamic normal and shear stresses at the socket/stump interface has begun. A number of different types of transducers have been investigated. Emphasis has been given to ease in clinical application. Arrays of Interlink force sensitive resistors (FSRs) with Kulite LQ-125 pressure transducers as calibration sources, are currently being used to sequentially sample normal stress and vertical shear stress at 6 cross-sectional levels in UF/TD and quadrilateral sockets during stance and gait. Work is also proceeding on design and development of a miniature horizontal shear stress transducer to complete characterization of total loading.

An automated force/tissue displacement probe has been designed and constructed for computer-controlled measurement of stump tissue compliance, and calculation and modeling of stump tissue viscoelasticities. Clinical testing with the probe has begun. Investigations of silicone and polyurethane thermoplastic elastomeres as materials permitting fabrication of controlled socket wall stiffness and elasticity have also begun.

Future Plans—It is planned to instrument and measure the static and dynamic socket/stump interface forces in UF/TD and quadrilateral sockets for 4 subjects. The data collected, together with the results of the stump tissue circulation and viscoelastic modeling studies, and the advanced materials studies, will be used to optimize the design of UF/TD sockets so as to minimize stump tissue stress concentrations and gradients, to support stump tissue circulation, and to generally enhance the comfort and function of geriatric A/K amputees.

Above-Knee Flexible Sockets: A Clinical and Technical Evaluation

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Sponsor: *Commonwealth Department of Veterans' Affairs, Australia*

Purpose—Thirty patients fitted with thermoplastic flexible sockets were followed up for periods ranging between 6 months and 3-and-a-half years.

Results—Flexible transparent sockets were found to be vastly superior to the conventional rigid laminated resin ones because: 1) Transparency makes them ipso-facto check sockets: a perfect fit is easily obtained. 2) Flexibility maintains continuous congruence between the stump and the socket. As a result, comfort is increased by continuous redistribution of weight, and security and stability are improved as loss of suction becomes negligible during gait, and minimal when sitting down and standing up. 3) The thermoplastic materials used are not allergenic. Two patients, allergic to fiberglass and resin have been wearing flexible sockets for 3-and-a-half years with no reaction. 4) Heat dissipates readily through the very thin walls. Excessive perspiration is avoided and potential dermatological problems such as cysts, rashes, skin irritation and erosions are prevented. Twelve patients who presented severe skin conditions in summertime with standard sockets are now free of problems with the new thermoplastic flexible sockets.

After periods of trial with the ISNY (Icelandic-Swedish-New York University) and IPSO techniques, we have developed a semi-rigid frame, capable of longitudinal as well as rotational shock absorption. A rational utilization of laminated fiberglass has resulted in the elimination of carbon fiber. A vacuum-molding technique was developed for obtaining an almost uniform thickness at all levels of the thermoplastic liner.

Implications—These very thin and flexible sockets are ideally suited for total contact and total surface weight bearing. The ischial tuberosity being no longer the main area for weight transmission to the prosthesis, ischial seats, quadrilateral brims, and rigid medial struts in the frame are no longer necessary. It is possible to produce sockets up to 400 g lighter than the conventional rigid A/K resin sockets by using the CDU technique.

Improved Upper Leg Prosthesis

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—A number of problems were observed with elderly users of upper-leg prostheses, namely: weight (too heavy); difficulty in putting on and taking off the prosthesis; and difficulty when sitting down. The aim of this project is to develop a prosthesis that does not have the above-mentioned disadvantages.

Progress—Initially, information was gleaned on a large international scale in order to start the drafting process in a well-informed manner. A list of demands for the prosthesis was defined, including production and manufacturing demands. A choice was made from several designs. In an evaluation phase, six of these prostheses were constructed, and the design was adapted on the basis of practical experience. The design proved to meet most of the demands and was presented at several symposia and congresses. Two courses for orthopaedic instrument-makers (with a total of about 30 students) were organized in cooperation with the Stichting Opleiding Metaal (Metal Training Institute) (S.O.M.), and in the meantime, approximately 20 prostheses have been made in The Netherlands according to this design.

This project was conducted in cooperation with Annakliniek.

C. Upper Limb

1. General

Implementation of Extended Physiological Proprioception for Prosthesis Control

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A302-RA)*

Purpose—Extended Physiological Proprioception (EPP) is a control concept that has demonstrated certain advantages for the position control of prostheses. The goal of this project is to control a Utah Arm with EPP, fit it to an above-elbow amputee, and evaluate its performance.

Progress—A unilateral above-elbow amputee is being utilized as a test subject. Laboratory tests have been performed with a Utah Arm, a Boston Arm, the amputee's body-powered prosthesis, and his contralateral, unaffected arm. Tests performed included tracking a random signal on a computer screen and blind positioning, in which he is asked to flex the elbow repeatedly to the same position without visual cues.

Results—The results with the Utah arm were markedly poorer than those with the other prostheses or his normal arm. Results with the Boston Arm, the body-powered prosthesis, and his normal arm were comparable with each other.

Future Plans—A new design for the transducer has been designed for the Boston Arm. The main features of the new design are that all of the hardware will be packaged in a 1 cm thick by 5 cm diameter cylindrical housing located at the elbow. A small control cable routed into the transducer housing will be the only hardware external to the prosthesis. The sensor for the transducer with be a force-sensitive resistor (FSR), which will provide a minimal dead band.

Publications Resulting from This Research

Extended Physiological Proprioception for the Control of Arm Prostheses. Carlson LE, Scott G, *Proceedings of the 11th Annual RESNA Conference*, Montreal, 90-91, 1988.

Powered Prosthetic Fingers

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Purpose—The primary purpose of this project is to develop externally-powered fingers (including thumb) that can be combined to create a functional, cosmetic partial-hand prosthesis for persons with transmetacarpal amputations. The secondary purpose is to determine if powered fingers (or thumb) can be used with amputees who have fingers remaining and also to examine whether they can be of use in devices for wrist and below-elbow amputations. The tertiary purpose is to investigate the possibility of a hand prosthesis with individually-controlled fingers. The fingers are to be the same size as those of an average adult. They are to have either one articulation (metacarpophalangeal [MP] joint) or two (MP and the proximal interphalangeal joint). The two-articulation system is being considered for its potentially superior grasping patterns. The performance goals are to develop at least 6.0 lbf per finger with an angular velocity of 1.0 radians/second or faster. The weight of each finger is not to exceed 2.0 ounces.

Progress—As this project has evolved, the emphasis has shifted from the concept of each finger as an individual unit into the idea of a total partial-hand prosthesis. A design has been finalized and a prototype partial-hand device is being fabricated.

The feasibility of individually-powered prosthetic fingers arose from the advent of motors 10 mm in diameter that were small enough to place in a prosthetic finger. However, calculations and experiments revealed that while an individual motor would be capable of providing either the velocity or force criterion, it would not be capable of meeting both specifications simultaneously. A review of current surgical/prosthetic practice in partial-hand amputations indicated, in general, only persons with loss of thumb and all fingers at or proximal to the MP joint required a functional prosthetic device.

The principle of synergy, as developed by this laboratory, was adopted to boost system performance. In a synergetic system there are two motors, one delivering high speed at low force, and the other providing high force at low speed. The powered prosthetic fingers used in a total partial-hand prosthesis requires at least three motors, one in the thumb and in each of the middle and index fingers, even if synergetic ideas are not used. In order to achieve maximum performance, the thumb motor provides the high speed, and the index and middle fingers deliver the high force. The total force delivered by the prostheses being given by the vector sum the force from each of the fingers. The drive system for the force side of the device is provided by a 10 mm gearmotor and drive screw. The pinch force varies with the pitch of the screw used (17.7 lbf pinch/finger is theoretically possible with an 80 thread/inch screw). The use of synergy precludes the use of double articulated fingers for compliance reasons.

Results/Future Plans—The first parts to be fabricated were the force drive systems. In actuality, tests performed with these components showed that only 9.1 lbf pinch per finger is possible with an 80 thread/inch screw, or 18.2 lbf per partial-hand device. While this is only 59 percent of the predicted theoretical results, it is still considerably better than the 12 lbf specified in the original proposal. These results are sufficiently encouraging to fabricate the remaining parts of the hand. The next stage is to test the fast side drive system and then to assemble and test a completed device. Since only three fingers are powered, amputees who still retain their ring and little fingers could also be fitted with this device.

Modular Electromechanical Lock Actuator

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A306-2DA, Part 2)*

Purpose—The fitting of multi-functional prosthetic arms to persons with high-level amputations continues to be a significant challenge to prosthetists and a frequent disappointment to users. In spite of a variety of body-powered and manually-positioned arm components that have been available for several decades, there are many deficiencies in these components that become all too apparent in high-level fittings. To facilitate finer placement of the prehensor or to extend its reach, a number of manually-positioned mechanical joints are available: wrist rotation units, wrist flexion units, humeral rotation units, and one-axis and multi-axes shoulders. These joints are pre-positioned against the body or against objects in the environment and either maintain their position from friction or by means of a positive locking mechanism. If positive locking is used, a mechanical control is provided for the user to release the lock. As with the cable-controlled elbow, these components are intended to be pre-positioned for a task, then locked in place during the task.

Arm prostheses which utilize the cable control system and manually-adjusted joints have many advantages. The cable control takes advantage of the user's otherwise intact musculoskeletal and sensory systems. Consequently, there is a close coupling between the user and the prosthesis. Based on experiences with prostheses for persons with high-level amputations, this laboratory believes that body-powered or manually-positioned components, with their comparative mechanical simplicity, general ruggedness, and lower cost, have not been fully exploited. The utility of cable-operated elbows and positive-locking wrist flexion and wrist rotation units is well established in prosthetic practice. The operation of the locking mechanisms in these devices, however, limits their effectiveness for the user and complicates the prosthetic fitting. To provide more efficient and versatile control of these components, a modular electromechanical lock actuator is being developed which can be used in conjunction with existing cable-operated elbows and positive-locking wrist components. The principal advantage of the lock actuator is the replacement of the high forces needed to operate the mechanical controls used now, with the considerably lower forces needed to operate an electrical switch controlling a motorized actuator. The force required to disengage the lock will be provided by the motor instead of by the user.

Progress/Preliminary Results—Design of the electromechanical actuator has been completed and one prototype has been fabricated. The device has been fitted to the locking mechanism of a cable-controlled elbow. Since in this application the locking/unlocking action is alternating, an electronic circuit was designed to "reset" the actuator. This makes the powered locking/unlocking action analogous to the manual locking maneuver: closing the switch momentarily will unlock the elbow and then the actuator would reverse to reset the ratchet, ready for the locking sequence at the next switch closure. The device has not as yet been fitted clinically.

A Modified Electric Hand

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Sponsor: *Commonwealth Department of Veterans' Affairs, Australia*

Purpose—Our purpose was to produce a satisfactory tactile feedback to the actions of the Myoelectric Hand Prostheses (MEP). The main limitation of MEP is lack of tactile-proprioceptive feedback. The weight of the electric hand at the end of a long lever arm is also a serious problem for patients with short forearm stumps.

Results—One adult patient with a very short below-elbow stump was fitted with a MEP and had pressure problems because of the perceived weight of the prosthesis. The motor was removed from the electric hand and relocated in a cylindrical housing in continuity with the distal end of the internal socket. As the motor represents approximately one-half of the weight of the electric hand, this redistribution of the weight of the prosthesis alleviated the pressure points on the stump. The vibrations of the revolving motor, amplified by the "sound box" of the housing-short socket complex, are transmitted to the skin of the stump as tactile stimuli. The perception of variations in revolution between extension, unopposed flexion and flexion against resistance produces a satisfactory tactile feedback to the actions of the MEP.

Further Research into the Use of Room Temperature Vulcanizing (RTV) Silicone Rubber as a Cosmetic Glove Material for Upper Limb Prostheses

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Sponsor: *Scottish Home and Health Department, Committee for Research for Equipment for the Disabled (CRED)*

Purpose—The purpose of this project is: 1) to quantify and evaluate the relevant mechanical properties of various commercially available RTV silicones; 2) to optimize the silicone for use with upper limb prostheses; and, 3) to streamline and standardize the manufacturing process.

The Bioengineering Centre has developed a process for manufacturing complete cosmetic gloves for functional and cosmetic prostheses from silicone rubber. The Centre has now gained experience over the last nine years in fitting over 50 patients, and results show that the average life of these cosmetic gloves is around 3 months. Despite the much-improved cosmesis and cleaning properties, the gloves tend to fail catastrophically rather than degrade gradually.

This research is intended to improve the strength and durability of the silicone rubber prosthetic coverings and to simplify the manufacturing process.

Methodology—After identifying 10 commercially available silicones, mechanical testing in the form of tensile, tear, and wear tests was undertaken to determine the optimum silicone for cosmetic glove use. Experimentally-formulated polymer versions of one of the commercially available silicones has also been tested.

A program of patient-fitting was undertaken to monitor acceptability and lifetime of the gloves. The manufacturing process has been examined and improved with no loss of cosmesis.

Results—Two silicones have emerged as being most suitable for cosmetic glove use. The first silicone is a fabrication called Cosmesil made by Cosmedica Ltd., at the University of Wales in Cardiff. This material is by far the strongest tested and can be formulated in varying degrees of softness and elasticity. Its basic color, however, is slightly grey which tends to bias the final coloring in an unsuitable manner for patients with lighter skin tones. It also tends to mask any internal highlighting at the knuckles, etc. However, new experimental polymer versions of Cosmesil which are virtually transparent are being tested by us and seem to have only slightly reduced strength with greatly improved color results.

The silicone supplied by the Danish company, Ringstead and Semler, has been used as a standard in glove-making since 1980. It is not as strong as Cosmesil in both tensile and tear tests by some 30 to 40 percent. However, the current manufacturing technique involves slush molding, and does achieve the best intrinsic color.

A small-scale fitting program has been implemented in an attempt to monitor glove durability, methods of failure, and patient acceptance. All the patients wore cosmetic prostheses as their primary prosthesis, but had worn conventional PVC gloves. Seven of these patients (3 male, 4 female) have been followed up for over a year. One has rejected the prosthesis, while the other 6 have demonstrated patterns of prolonged, frequent use and have derived significant benefit from the enhanced cosmesis. These trials are continuing.

The manufacturing process has been standardized and excellent repeatability of quality and color are now possible. In addition, research has been undertaken into speeding up the manufacturing process.

Future Plans—It is our intention to complete the testing of the new research polymers, and thus formulate the "ideal" polymer for glove manufacture.

Further ideas on reducing glove manufacture time and simplifying the process are also being tried, e.g., silicone spraying. The grant has been extended to December 1988, and by that time it is hoped that a commercially viable process will have been perfected.

Optimizing Myoprosthetic Management with Microcomputers

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Sponsor: *The Hospital for Sick Children Foundation*

Purpose—This project is aimed at establishing new strategies and objective standards for the analysis of myoelectric prosthesis operation. The specific aims are to: 1) develop a reliable and objective test of an amputee's ability to control a myoelectric control system; 2) establish and develop a standard database of an amputee's abilities to operate a myoelectric prosthesis; and, 3) develop and test during the project's second year, a microcomputer-based muscle site identifier and control system calibrator.

Progress—This 2-year project is being conducted at the Hugh MacMillan Medical Centre (HMMC) with the participation of two groups of 30 amputees. Each group consists of experienced below-elbow users of myoelectric prostheses, equipped with an Otto-Bock 2-state control system, who are 5 years of age or older.

The first 30 subjects have been tested with a microcomputer-based Myoelectric Control Assessment Program (MCAP). MCAP allows the amputee to interactively control a visual hand stimulus using myoelectric control. The target and hand position, number, and duration of events, and elapsed time are recorded by the computer for subsequent analysis. Subjects in this group were asked to visit the Centre on three occasions (i.e., Day One, one month later, and three months after Day One) and complete six test sessions on each occasion.

Preliminary Results—An initial estimate of the reliability of 8 variables measured within Day One and within Month One data indicate that the MCAP test is reliable with correlations ranging from 0.6 to 0.8. Given the presence of the significant learning effect ($p<0.001$) over the sessions, the initial correlations are considered to be very encouraging.

The difference in total number of events as a consequence of the magnitude of initial finger and thumb displacement was significant ($p<0.001$) with larger displacements requiring a greater number of opening or closing responses. The nature of the movement (i.e., opening or closing the hand) was significant ($p<0.005$).

To date, we have shown that MCAP can be used to facilitate the collection of reliable information concerning amputees' abilities to operate myoelectric prostheses. We have also noted the importance of proper control system calibration, even for 2-muscle 2-state operated prostheses.

Future Plans—The second group of amputees will be tested during the second year to allow evaluation of the HMMC Myoelectric Assessment System. This system encompasses the necessary tools required by a clinician to objectively: 1) find the most appropriate muscle site; 2) determine the amputee's muscles myoelectric signal levels; 3) determine the variation of the myoelectric signal produced during a sustained muscle contraction; 4) determine antagonist muscle signal cross-talk; 5) determine the calibration levels for the myoelectric control system; and, 6) visually verify the calibration levels as well as providing for manual adjustment of levels if necessary. Both traditional and microcomputer modalities will be used to allow investigation of the differences between these two approaches.

Publications Resulting from This Research

Microcomputer-Based Muscle Site Identification for Electrode Placement in Myoelectric Prosthesis. Kurtz I, Mifsud M, Hubbard S, Hamilton E, Naumann S. *Proceedings of ICAART 88*, Montreal, 88-89, 1988.

Elbow-Controlled Hand Prosthesis for Children

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is to make good elbow-controlled hand prostheses available for children. The intention is to develop a device that scores high marks for comfort in use, for design, and for ease of operation.

Progress/Results—The design for an improved elbow-controlled hand prosthesis for children in the age bracket between 7 and 10, is almost ready. From this design, the construction drawings for a smaller design (up to 6 years) will be deducted by means of scale laws.

This work is being conducted with the cooperation of Rehabilitation Centre de Hoogstraat, Leersum (now Utrecht), St. Maartens Clinic, Nijmegen.

Publications Resulting from This Research

Triceps Power of Children (Abstract). Kruit J, *Third European Conference Research in Rehabilitation*, Rotterdam, 1988.

Elbow-Controlled Hand Prostheses for Children (Abstract). Kruit J, Cool JC, *Symposium on the Limb-Deficient Child*, Heidelberg, 1988.

Research into a Modular Prosthetic Development for the Upper Limb

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Sponsor: *Lothian Health Board*

Purpose—From previous experience gained in the manufacture of body-powered prostheses and externally-powered prototype limbs, it was decided that a series of component parts could be devised that would be interchangeable between different sizes and different power regimens. Therefore, our purpose was to develop a useful system of interchangeable components for control, cosmesis, power, and structure of artificial upper limbs.

Specifically, the aim of this work was to develop six sizes of hand prosthesis from child to adult male, and to develop powered wrist, elbow, and shoulder joint components. The work was split into four areas: cosmesis, control, power, and structure. Cosmesis was to be based on room temperature vulcanizing silicone elastomer. Control was to be based on interchangeability between control regimens such as extended physiological proprioception (EPP), electromyogram (EMG), or switch control. Power was based on body power and miniature gearboxes and 0.5 to 3 and 10-watt DC motors powering ballnut or ballscrew actuators. Structure was to be based upon interchangeability of components between sizes and power types, e.g., body-powered hand structure is identical to electrical-powered hand structure.

Methodology—Those parameters which were critical to the concept of modularity were identified and finalized. The aim was to produce a structural component common to all six sizes of hand which, with the addition of the appropriate knuckle unit and fingers, would become the hand size required. This structural component, known as the torque box, would also be used in both body-powered and electrical configurations.

For the design of other upper-limb-powered joints, it was decided to replicate the movements of the Edinburgh pneumatic arm by using ballnut type actuators and appropriate motors.

Results—Prototype versions of the midrange Size 3 hand in body-powered and electrical configurations have been laboratory tested and clinically fitted to one female patient. The design has been successfully revised to achieve interchangeability of the main structural component between Sizes 3 to 6. Sizes 1 and 2 are being based on the "powered knuckle" concept. A number of units are presently under construction for trial fittings.

The electric hand is powered by a ballnut with an anti-runback feature, and this novel device has been incorporated into a prototype elbow mechanism based on the design used in the Edinburgh pneumatic arms in the 1970's. The system can be driven by one or two 3-watt motors and has been successfully bench-tested. The unit weighs 320 grams. Designs for a shoulder-elevation actuator, using a ballnut and a 10-watt DC motor and a wrist rotation actuator, have been formulated. Manufacture and testing of the prototype limb is scheduled for Spring, 1989.

Future Plans—It is proposed to have the final structural component manufactured as an investment casting. An initial batch of twelve hands would then be fitted to patients in the Size 3 and Size 6 categories (six of each). The hands would be fitted in both body-powered and electrical configurations (three of each). The electric hand fittings would be controlled by myoelectric, switch, and proportional (EPP) control packages (one of each). Work will also be carried out to develop molds to allow injection-molding of shape fairings and fingers.

Improvement of Body-Powered Upper Limb Prostheses

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The goal is to improve the acceptance and use of body-powered upper limb prostheses by arm amputees in the USA. The objective of this project is to improve conventional arm prostheses by means of a: 1) hydraulic force transmission system to replace the present cable control system; 2) prehensor which is neither hook nor hand; and, 3) elbow extension control to eliminate the shoulder harness.

Progress—Prototypes are being made for evaluation of a hydraulic control system, a rotating thumb prehensor, and an elbow extension controlled prosthesis.

Preliminary Results—1) The hydraulic control system is conceptually great but difficult to implement inside the prosthesis; 2) the prototype prehensor received good reception in a poll of amputees, occupational therapists, and prosthetists; and, 3) the elbow extension control has real promise if the elbow-latching mechanism can be made successfully.

Future Plans—Complete all prototypes, assess potential use, and report results in next year of project.

Publications Resulting from This Research

Do We Need a Prosthetic Prehensor Which Is Neither Hook Nor Hand? LeBlanc M, Parker D, Nelson C, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:204-206, 1987.

Making the Case for Body-Powered Upper Limb Prostheses. LeBlanc M, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 196-198, 1987.

Assessment of Three New Designs of Prosthetic Prehensors for Upper Limb Amputees. Meeks D, LeBlanc M, *Prosthet Orthot Internat* 12(1):41-45, 1988.

Rotary Hand Prosthesis. Patent applied for: March 21, 1988.

Simulation of a Microcomputer-Controlled Prosthesis with Extended Physiological Proprioception

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Sponsor: *The Natural Sciences and Engineering Research Council, Canada; The Royal Ottawa Health Care Group; University of Ottawa*

Purpose—The purpose of this part of the project was to perform additional tests on the control of a prosthesis using extended physiological proprioception. The present strategy involves a computer simulation of the prosthesis, instead of a bench model as had previously been used. A computer simulation has a number of advantages over bench models. For example: noise cues—which could invalidate the results—can be eliminated; no additional cues are received by the subject when he or she reaches the target; performance and error measures can be computed easily and accurately; system dynamics can easily be changed and can even include components not yet developed; the target and/or the prosthesis can be removed from view simply by eliminating it from the screen, and so forth.

Progress—A simulation has been implemented on a PC-XT computer. Great care has been taken to ensure that the simulated image of the prosthesis has the same "feel" as a real prosthesis. Tests are currently being performed using this system and they attest to the usefulness and validity of this experimental strategy.

Future Plans—It is planned to use the simulation system to perform in-depth research on the characteristics of extended physiological proprioception.

Publications Resulting from This Research

An Above-Elbow Prosthesis Employing Programmed Linkages. Gibbons DT, O'Riain MD, Philippe-Auguste S, *IEEE Trans Biomed Eng* 34(7):493-498, 1987.

Position Proprioception in a Microcomputer-Controlled Prosthesis. O'Riain MD, Gibbons DT, *Med Biol Eng Comput* 25:294-298, 1987.

Simulation and Modeling of a Microcomputer-Controlled Above Elbow Prosthesis. Philippe-Auguste JS, Gibbons DT, O'Riain MD, *Automedica* (in press).

A Multi-Functional Prosthesis Employing Extended Physiological Proprioception and Programmed Linkages. Gibbons DT, O'Riain MD, Philippe-Auguste JS, Workshop presented at the joint coordinating forum for the International Advanced Robotics Program, *First International Workshop on Robotic Applications in Medical and Health Care*, 16.1-16.5, Ottawa, Ontario, 1988.

The Development of a Cosmetic, Functional Prosthesis for Children

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Sponsor: *REACH: The Association for Children with Artificial Arms*

Purpose—It is our purpose to design, develop, and fit a cosmetic, functional prosthesis for children.

The experience of the Bioengineering Centre in producing functional prostheses with enhanced cosmesis has to date, mainly been confined to adults. The knowledge gained has now been applied to the construction and testing of a miniature electric hand for children.

In line with Edinburgh's other areas of research on modular prosthetic systems, the powered knuckle device developed in this project is intended to form a building block which can be augmented by adding spacing units to achieve hands suitable for all lengths of stump and control regimes. Cosmesis is based on silicone rubber.

Results—Three patients, all congenital transcarpal amputees, have been fitted since September, 1987. The age range is 10 to 12 years, and they are fitted with a hand termed Size 2 in our modular range (Size 1 is smallest and Size 6 is largest). A version of the powered knuckle with an anti-runback locking feature has been designed and built.

The three patients (all girls) and their parents have given us excellent feedback about the devices. There have been several failures due to breakage (falls, etc.) and several due to malfunction of electronics and/or motors. Overall, the pattern of wear has been infrequent, although school use seems to be the most often cited. The use of Otto Bock batteries has made the devices heavy and the sockets a little cumbersome for patients with such little disability.

None of the three patients are particularly interested in cosmesis at this stage (one is a proficient volar plate user). All three have exhibited good control of the prostheses using carpal flexion/extension to control a single switch which acts through a "flip-flop" module to give alternative open/close operations.

Future Plans—We are now building versions of the powered knuckle in Sizes 3 and 6 for our modular range. It is envisaged that these will be built and fitted by Spring 1989.

A version of the Size 2 hand with a locking feature has been built and this will be fitted shortly. It has been proposed that the hand electronics be reduced in size by using surface-mounted devices, and include the electronics package in the hand itself. Similarly, a battery module based on high energy density rechargeable lithium batteries is being developed for inclusion into the hand. It is also proposed that the program be expanded to allow both myoelectric and extended physiological proprioception (EPP)-controlled powered knuckles to be fitted.

Acquisition and Analysis of Displacement Shoulder Signals for the Proportional Activation of Prostheses

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Sponsors: *Technion VPR Fund; Isler Foundation; Kennedy-Leigh Research Fund*

Purpose—Following the concept of extended physiological proprioception, the 2-dimensional human shoulder's motion (anterior-posterior and elevation-depression) may be used for the proportional activation of a 2-degree-of-freedom artificial arm. In a feasibility study, a system for the acquisition of displacement signals from the shoulder of a healthy subject was constructed and analyzed.

Methodology—We use self-made high-elongation liquid metal displacement transducers with an average length of 12 cm and linear extensibility of 30 percent. These transducers are anchored at their extremities to landmark anchors (altogether 7 points), located above bony prominences on the acromion, sternum, clavicle, and scapula, as well as along the vertebral column; and are attached to a well-fitted diving jacket, worn by the tested subject. Of the different configurations which can be obtained, 4 are being studied: 3 consist of 2 transducers each, one for vertical and one for horizontal displacement. In the fourth configuration, 3 transducers are being used, the horizontal displacement being measured by using 2 transducers, differentially connected.

Performance of the system is evaluated in 4 basic motion patterns: horizontal, vertical, circular, and random. A "SELSPOT" opto-electronic system is being used in parallel to objectively measure the motion of the shoulder.

Results—Parameters used for assessment of the system and comparison of its configurations are: determinant of the linear transformation matrix, error and standard deviation, cross-correlation between the system and "SELSPOT" outputs and crosstalk between the transducers. Results indicate that the fourth configuration is superior as compared to the others, with correlation coefficients above 0.95 and with smallest crosstalk. This was consistent in all motion patterns tested, indicating that there exists a general transformation matrix by which the output of the transducers can describe the motion of the shoulder joint.

Future Plans/Implications—The results obtained for the system developed and analyzed indicate that displacement shoulder signals can be reliably used for the proportional activation of 2-degree-of-freedom prostheses (artificial arms or neural prostheses, such as FES). Liquid metal transducers prove to be adequate, especially due to their minimal thicknesses. However, since a diving jacket, as a means of attachment to the body, may sometimes be inconvenient, alternative methods ought to be explored as well.

C. Upper Limb

2. Above-Elbow

Design of Advanced Body-Powered Prosthetic Arms

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A421-D)*

Purpose—The primary objective of this study is to design and test a body-powered prosthetic elbow. Three sub-projects will investigate: the structure, actuation and lock mechanisms, and actuation cables.

Methodology—Materials and manufacturing techniques that can be used to produce a lighter and stronger structure for the same or lower cost than present body-powered arms will be investigated. Plastics and composite materials are being considered. Injection molding and blow molding are possible manufacturing techniques.

Progress—An internal actuation mechanism that will provide adjustable cable gain, lift lock capabilities, and elbow and terminal device cable-pull independence is being designed. The same mechanism will provide simple adjustments for amputees with large cable excursions as well as for amputees with limited cable-pull excursions. Elbow and terminal device independence will provide amputees with limited cable excursion full terminal device actuation at any elbow angle.

We are also investigating polymer materials for replacement of the currently-used steel cables. Materials used for the tendons in the Utah/MIT Dextrous Hand (robot hand) are being tested for their durability and utility in prosthetic systems.

Two Degree of Freedom, EPP-Based Arm Prosthesis for Above-Elbow Amputees

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Sponsor: *National Institutes of Health*

Purpose—The general intention of this study is to develop an externally powered mechanical arm prosthesis with two degrees of freedom. It will consist of a powered elbow and a 3-finger, single-joint prehensile device.

A control system using the principles of Extended Physiological Proprioception (EPP) is being developed to provide the greatest range and restoration of function. The concept is based on the use of residual joints with intact proprioception to provide the subject with an intuitive knowledge of the position of the artificial arm as long as there is a "rigid" attachment to a member of the body.

Progress—A transducer and a mounting system were developed to monitor 2-degrees-of-freedom of motion of the acromion (of the shoulder).

An analog controller was developed that acts as a null balance system. It compares the intended position of the arm and actual position of the arm. When either signal exceeds the allowable error tolerance, the motor is activated in the proper direction until the signals are once again within the proper range. A computer-based controller, with more control over the drive motor was also developed.

Results—A preliminary evaluation of the arm system was conducted. The control circuits and the transducers functioned with a high degree of linearity. A model was created and tested with the aid of a computer, a MacIntosh with a MacAdios interface. The model was able to accurately predict the actions of the controller. The computer-based controller demonstrated a much finer control than earlier systems.

The arm system currently under development has shown promise in meeting the design requirements of a position control arm for above-elbow amputees. It is compact, with good functionality, and it will be easy to learn how to use it due to the intuitive nature of the control system.

II. Orthotics

San Francisco Molded Shoe Therapeutic Evaluation and Diabetic Risk Stratification

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A010-3DA)*

Purpose—Our purpose is to evaluate the San Francisco Molded Shoe on a specific at-risk population and to modify design characteristics and fabrication technology to improve therapeutic effectiveness, lower costs, accelerate fabrication time, and improve patient acceptance. A second purpose is to obtain data which can be used to predict the probability of future tissue breakdown in the diabetic foot.

Part 1: Therapeutic Molded Shoe

Progress—The shoe being developed is designed for diabetic patients with insensate feet who have had a history of plantar foot ulceration but who have not yet undergone major foot amputations or developed marked foot deformities. This project is directed toward patients with moderate to severe peripheral sensory neuropathy diagnosed and graded via specific sensory testing procedures (Semmes/Weinstein probes). Three areas of development in custom shoe fabrication have been improved: 1) precise foot positioning and standardization of the casting procedure; 2) utilization of a unique casting material; and, 3) the incorporation of mass production technology in fabricating individual custom shoes.

Precise foot positioning and standardization of the casting procedure is accomplished by an electronic ultrasound measuring instrument positioning the leg, ankle, and foot as well as arch height to insure proper contour of the insole and biomechanical function of the foot. Use of this instrument insures accurate reproducibility.

A unique tubular polyurethane material used to cast the foot. This material has several advantages over conventional plaster: 1) it eliminates the need for a "negative" cast, saving time and expense in labor and materials; 2) easier workability for modification purposes; 3) safer removal from the insensate foot and leg; 4) improved strength; 5) cleanliness; and, 6) elimination of dust.

The tubular casting material allows rapid modification of its basic shape. Use of prelasted, mass produced uppers eliminates the need for designing and cutting individual patterns. The insole and midsole use expansile polyurethane foams to provide the best combination of cushioning and support.

Results—The current prototype shoe has undergone clinical trials involving 7 subjects with a very high degree of acceptance. In-shoe pressure evaluation, using pressure sensitive transducers, are being undertaken to quantify the therapeutic effectiveness of the shoe in reducing local areas of pressure.

Part 2: Risk Stratification

Progress—This aspect of our project defines the prevalence of foot pathology, lower extremity complications, and known risk factors for ulceration in a cross sectional analysis of 92 diabetic patients from our metabolic clinic.

Results—Sixteen percent of patients had a history of complications, including pedal ulceration and/or amputation, previously requiring 1,480 hospital days of care. Sixty-eight percent of patients had structural pathology in the foot; 34 percent were insensate 25 percent had autonomic neuropathy; 22 percent had atherosclerosis obliterans as defined by an ankle brachial indices less than 0.9; and 13 percent suffered from intermittent claudication. The following pathologies were significantly more prevalent in diabetic patients with a history of ulceration and/or amputation compared to those patients without ulceration or amputation: hammertoe deformity ($p<0.001$), abnormal cutaneous pressure sensation ($p<0.05$), abnormal R-R interval ($p<0.05$), intermittent claudication ($p<0.05$) and abnormal ankle brachial index ($p<0.05$). An important finding was that 41 percent of insensate patients were not aware of their sensory deficit. The high prevalence of lower extremity pathology appears to emphasize the need to identify high risk patients for early entry into patient education and prevention programs.

Publications Resulting from This Research

High-Resolution Ultrasound in the Preoperative and Postoperative Assessment of Distal Metatarsal Osteotomy: Preliminary Report. Graf PM, Farac K, Stess R, Gooding GAW, *Invest Radiol* (accepted for publication).

Design of External Joint Assemblies (EJAs)

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A167-RA)*

Purpose—The goal of this project is to test the hypothesis that customized external joint assemblies, including knee braces, lead to improved performance. The first tasks were to develop systems for the design and fabrication of customized hinges and cuffs for a knee brace.

Progress—Apparatus was constructed to provide a characterization of knee kinematics with data, in a format that would lend itself to being employed in the fabrication of a customized hinge to duplicate the motion. A second device was designed and constructed for measuring the 3-D body surface shape ("Magic Fingers"). The accuracy of the data generated by these two devices is currently being verified. In addition, manufacturing methods are being explored to best utilize the output of these devices for the fabrication of the knee brace.

In an associated project, a myoelectric upper extremity orthoses for C5-C7 spinal cord injured patients has been developed. Investigations are underway to access how this device can best be implemented by patients.

Future Plans—Once the customized knee brace is fabricated, the hypothesis will be tested by comparing the kinematics of knee motion of patients fitted with conventional and the newly-developed customized braces. The braces will be instrumented with strain gauges to access the load pattern on the frame as an additional means of assessing the relative performance of the EJAs.

Functional Kinesiology of Knee Bracing

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A386-RA)*

Purpose—The objective of this project is to investigate the effects of five functional braces on the kinesiology of the injured knee. Measurements will be made using a 6-degree-of-freedom goniometry and electromyography during walking and pivoting.

Progress—The first major challenge is to measure the kinematics of the braced knee. A 6-degree-of-freedom goniometer has been designed, fabricated, and tested. The goniometer underwent many design changes and tests in order to insure that it can be mounted around the knee joint braced with a variety of orthoses, the measurements are not affected by soft tissue motions, and it does not make contact with the orthoses.

Future Plans/Implications—The next year will be devoted to testing the effect of knee braces upon kinematics of the injured knee joint. A measurement protocol has been developed to measure kinematic motions of specific anatomic points. In the long term, this will result in the ability to measure the relative motions of points on the tibial and femoral articulating surfaces. Presently, it provides the motions of tibial landmarks with respect to femoral landmarks.

Walker for the Young Cerebral Palsied Adult

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Sponsor: *Committee for New Developments in Health Care*

Purpose—Our purpose is to investigate the factors that affect the mobility of cerebral palsied individuals in order to design improved mobility aids. The results of this research will be aimed particularly at designing a mobility aid for the young cerebral palsied adult—persons who, due to their size, and the related weight and stability problems, have been generally ignored in the commercial market.

Progress—An "assessment walker" has been designed and produced that allows considerable control over the posture and orientation of the occupant. The device can be tilted independently of the multi-adjustable body support sections. Saddle height adjustment is from 600 mm to 740 mm, allowing access to older children and young adults. This range was chosen because it gave access to the greatest number of subjects to test in our area.

In order to quantify the effects of different walker configurations, a clinical electromyogram (EMG)/footswitch system has been developed. The equipment for this includes an Archimedes A310 microcomputer, an MIE 8-channel telemetry system, and an infra-red footswitch telemetry system developed by the Bioengineering Centre. Software has been written which allows the investigator to produce printouts of the averaged EMG data for the transduced muscles within minutes of a test taking place, allowing for on-the-spot interpretations of alterations to be made.

Preliminary Results—The walker has been tested for a number of months at various institutions; testing of the measurement system began recently. It is intended that the averaged EMG profiles will help us to understand the effects of different walker configurations, leading to the design of improved walking aids.

Further Development of a Protective Helmet for Disabled Persons

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Sponsor: *National Health Research and Development Programme (Health and Welfare Canada)*

Purpose—To continue development of a helmet which will provide head and facial protection for children with a high risk of injury due to falls.

Progress—As part of an earlier study, a first generation helmet was produced and assessed with the assistance of 10 individuals who wore it regularly for two months. An informal survey of the performance of the prototype helmet was undertaken two years after the initial fittings. Based on the results of this preliminary work, development of the second generation prototype will focus on enhancement of its impact properties and structural integrity. Improvements in liner fit, ventilation, and hygiene will be made without compromising the helmet's general cosmesis.

A review of anthropometric data on head sizes of children aged 5 through 19 years enabled the team to establish a goal of developing protective headwear for nominal head circumferences of 490 mm to 580 mm. Initial indications are that only two helmet sizes will be needed to fit children with head circumferences in this range.

A mock-up of a modified, first generation (original) helmet was created to incorporate some of the conceptualized modifications proposed for the purpose of stimulating discussion among project team members. Alternatives to full contact cranial and facial protection are presently being examined in an effort to enhance ventilation and minimize the complexity of the helmet's construction. As a result, alternative shell and liner materials and the means for fabricating them are presently being investigated.

Preliminary Study of a Hand Orthesis for Prevention of the Consequences of Rheumatism

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Evaluation of the usability and wearing comfort of the experimental rheumatism hand orthesis 55R07 by clients without hand abnormalities.

Progress—This was only a study in order to gain a first impression of the quality of the materials which can be used to manufacture a rheumatism orthesis.

The investigation was not continued because the researching institution does not have the time or money available necessary for the execution of this kind of research.

Modular Standing Frame

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The prime purpose of this project was the development and marketing of a modularly-constructed standing frame for spastic children, with special attention being directed toward functionality (mentally, socially and medically; cost price; appearance; improvement of quality of life of users; and universal usability and possibilities for distribution).

Progress—This product was introduced onto the market in Spring 1988, and at fairs in The Netherlands, Federal Republic of Germany, Denmark and France, and was developed in cooperation with Meyra Nederland and Rehabilitation Centres.

Feasibility Research into the Application Possibilities of CAD/CAM Technology in the Production of Orthopaedic Footwear

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Sponsor: *Innovative Research Programme Aids for the Handicapped*

Purpose—This research should provide an answer to the question of whether CAD/CAM technologies can be used for measuring the shape and size of feet, and for the modeling and producing of the lasts for the production of orthopaedic footwear.

Results—Orthopaedic shoe technicians already use CAD/CAM (especially in the shoe industry, and in the making of orthopaedic instruments). The development of CAD/CAM for orthopaedic shoes has already started in a number of places abroad. The expectation is that it will be several years before there are ready-made CAD/CAM systems that can be used in practice. CAD/CAM will be used for the measuring, designing, and making of lasts; the production of supplements and patterns; and for the application of orthopaedic footwear in B-design. Instead of individual fitting, a B-design is concerned with adapting orthopaedic shoes that have been produced in small numbers to the individual.

Due to the current status of development, no conclusions can yet be drawn concerning the business-economical aspects. It is essential that future developments are monitored carefully, and experience with CAD/CAM for orthopaedic shoe-techniques be gained in The Netherlands. It is advisable to start with one or more small projects. In the final report, a number of these follow-up projects are suggested.

This study was conducted in cooperation with the Rehabilitation Centre Amsterdam.

The Influence of Rocker Position and Height on the Gait of Cerebral Palsied Children Wearing Ankle Foot Orthoses

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Sponsor: *James and Grace Anderson Trust*

Purpose—We are studying the influence of rocker sole characteristics on the gait of cerebral palsied (CP) children who wear ankle-foot orthoses (AFOs), to develop clinical guidelines for their use.

Progress—Using the biomechanical gait analysis facility at the Princess Margaret Rose Orthopaedic Hospital, the gaits of 10 hemiplegic and 10 diplegic children will be analyzed. A purpose-built sandal will permit the rocker characteristics to be altered in a predetermined fashion. The analysis will include information on walking speed, cadence, angular motion of joints, and the ground reaction forces and joint moments being generated.

New, Lightweight, Inexpensive, Modular KAFOs for Persons with Paraplegia

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Sponsor: *National Institute on Disability and Rehabilitation Research; The Meadow Foundation*

Purpose—Our research is designed to demonstrate the feasibility of a new innovative approach to the problem of providing orthotic assistance for the patient with paraplegia, early in the course of a comprehensive rehabilitation program. All health care institutions treating persons with paraplegia will be interested in the results of our study. Every day, professionals in these centers are faced with making judgments about the propriety of goals regarding ambulation possibilities for patients with paraplegia. These priorities determine the allocation of resources (time and effort of staff, as well as purchase of special equipment) to assist the patient in accomplishing those goals. The use of multi-adjustable knee-ankle-foot orthoses (KAFOs) (clunkers) does not provide the necessary clues because of complexity and inadequacy of the adjustments necessary. Thus, important information needed to judge the appropriateness of providing the individual paraplegic patient with bilateral custom-fitted Craig-Scott-type leg braces is most often lacking. Consequently, the decision is usually made to prescribe custom metal orthoses to provide the patient with a valid opportunity to experience "what it will be like" to use braces and crutches as a primary means of mobility. The wisdom of that judgment can be seriously questioned, when learning that many patients discard their expensive conventional orthoses as being impractical, shortly after being discharged from the rehabilitation program.

Progress—In this study, we have designed, fabricated, and pilot-tested an inexpensive lightweight, modular KAFO that will assist paraplegic patients in: 1) standing during early stages of their rehabilitation; 2) exercise ambulation for improvement of endurance for physical activities, including swimming pool activities; 3) gait training; and, 4) ambulation within home or community.

A new approach to orthotic management of paraplegic patients is used, in which the modular KAFO is initially supplied (virtually "off-the-shelf"), so that inpatients can participate in a standing program very early in their rehabilitation. The initial standing program and gait training activities of these patients are performed using braces with the knees locked. Therefore early design considerations have focused on the development of side members which have no knee joint. Modifications and adjustments of the modular components can be made in the clinic to obtain a proper fit in a matter of hours. No shoe attachment is required, because the foot-ankle support fits inside the shoes. Our new orthosis is custom-fitted to the user, and the end product is substantially lighter, cheaper, and more cosmetically acceptable than conventional metal braces. At the same time, the device is strong enough to meet the ordinary needs of users, providing safe stabilization of the lower extremities.

Future Plans—An important potential outcome of our research project is to make good quality, inexpensive, lightweight, custom-fitted standing/walking leg frames/KAFOs available for use in less-developed countries that do not have access to conventional orthotic services. We expect our modular components to be supplied at modest expense to nearly any setting. The components will be selected from a limited number of sizes, and custom-fitted to the patient in the clinic, using simple tools. The fitting procedures are simple enough that a technician with mechanical aptitude can very probably be trained in a matter of a few days to assemble and fit them. Thus, better services can be anticipated to become available to persons with paraplegia in underdeveloped countries—as well as in our own.

Biomechanical Evaluation of Synthetic Cast Materials

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Sponsor: *None Listed*

Purpose—Historically, plaster-of-Paris has been by far the most convenient and effective casting material available. In recent years, however, new synthetic fiberglass and polyester casting materials have been developed. Thus, the orthopedist now has a wide range of choice among synthetic cast materials when a lighter and more durable form of cast is preferred. However, a rational choice is difficult, since no information is available on their mechanical properties. This prompted us to initiate this investigation to determine the load-deformation characteristics of various synthetic casting materials.

Methodology—Six fiberglass (Alphacast, C-Cast, Delta-lite Red, MaxCast, Scotchcast 2, and Zimmer), and two polyester (CutterCast and Delta-lite Black) synthetic casting materials were examined. Three-inch internal diameter synthetic cast cylinders were prepared and these were tested in diametral compression using an Instron testing machine. The load-deformation curves from each group of six cylinders were then used to determine the load applied at deformations of 5, 10, and 15 mm. The stiffness of each casting material was taken as the slope of the curve at 5 mm deformation point.

Results—Of the six brands of fiberglass casting material, Zimmer was by far the strongest; Delta-lite Red and MaxCast were the next in strength. The two polyester casting materials (Delta-lite Black and CutterCast) were much weaker than the fiberglass casting materials.

Future Plans/Implications—Our studies indicate that when choosing synthetic casting materials, the load-deformation characteristics must be considered. There are other factors that also must be considered such as setting time, cost, moldability, durability, and shelf-life. Further investigations are planned to examine these variables.

Orthokinetic Orthoses: Clinical Efficacy Study of Orthokinetics Treatment for Post-Cerebral Vascular Accident (CVA) Upper and Lower Extremity Dyskinesia and Chronic Pain

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Sponsor: *Orthokinetics Research Foundation*

Purpose—This study investigated the efficacy of application of orthokinetic orthoses to the hemiparetic left upper and lower extremities of a patient 2.5 years post-CVA, with upper and lower extremity dyskinesia, severe chronic shoulder-hand pain, and severe pain from hip to toes.

Progress—The patient had upper extremity flexor synergy and tonus which precluded any active motion in the upright position: no active ankle dorsiflexion; and hemiplegic gait. She had chronic hyperalgesia of the entire left side (from face to toes), chronic shoulder-hand pain, and deep lower extremity pain (in leg and foot), which could not be relieved by physical therapy treatments prior to application of orthokinetics orthoses. The treatments of dyskinesia and pain of the affected upper extremity comprised a single-subject time-series pilot study which was followed up by clinical orthokinetics treatments over 22 weeks, designed on the basis of the outcome of the pilot study.

Results—The patient was a 60-year-old female with left hemiparesis, 30 months post-CVA. An experimental orthokinetics treatment, of single-subject design, was administered to the upper extremity, comprising the time-series A1-C1-A2-B1-A3-C2-A4-B2-C2′-B3; A1 to A4 = nontreatment phases; C1 = placebo treatment phase; C2, C2′ = sham treatment phases; B1 to B3 = orthokinetics treatment phases. The orthokinetics treatments were based on the following rationales: the neurophysiological mechanism of orthokinetics treatment for dyskinesia invokes the difference in elasticity between the active and inactive fields of the orthokinetic cuff, overlying muscle agonist(s) and antagonist(s) respectively, with resulting facilitation of the agonist(s) by selective cutaneous stimulation of mechanoreceptors via excitation of $\alpha-$ and $\gamma-$ motoneurons, and reciprocal inhibition of antagonist(s). Orthokinesis analgesia is proposed to occur by input of stimuli from the orthokinetic orthoses (cuffs) to cutaneous non-nociceptors; these peripheral stimuli modulate the dorsal horn enkephalinergic interneural mechanism of anti-nociception. During orthokinetics treatment, 4 orthokinetic cuffs were applied, 2 each to the patient's arm and forearm, positioned to facilitate elbow, wrist, and finger extension. The treatments were applied to the patient single blind. The outcomes were consonant with the described neurophysiological theories of orthokinesis remediation of dyskinesia, and of orthokinesis analgesia. Internal validity (cause-effect relationship) was tested by inclusion of the nontreatment phases, placebo treatment phase, and sham treatment phases, with the orthokinetics treatment phases. During phases A1 through A4, active range of motion (AROM) of the elbow was 0 degrees (i.e., no remediation), implying: a) that no placebo effect was detectable, and, b) that 5-minute duration of orthokinetics treatment B1 provided insufficient orthokinetic facilitation; in contrast, in orthokinetics treatment B2 (5 minutes), AROM of the elbow increased to 75 degrees, reversed to 0 degrees in sham treatment phase C2', and returned to 75 degrees AROM of the elbow in orthokinetics treatment replication phase B3. The active elbow range of motion achieved during the pilot study increased to 135 degrees over the course of subsequent treatments, with carry-over. Active ankle dorsiflexion, with control of inversion, as well as active forefoot and toe lift of 6.5 cm was achieved with application of 2 orthokinetic cuffs on the leg to facilitate ankle dorsiflexion and toe extension. Hyperalgesia was remediated completely with the initial pilot treatment. Chronic shoulder-hand pain and leg pain were substantially remediated in subsequent treatment sessions.

Future Plans—Future plans for the project include further investigations of internal, external, and clinical validity of orthokinetic orthotics in treatment of persons with traumatic brain injury for dyskinesia, spasticity, and chronic pain. These studies are part of an ongoing combined cognitive-perceptual-motor rehabilitation program for survivors of closed head injury.

Publication Resulting from This Research

A Multidisciplinary Efficacy Study on Orthokinetics Treatment of a Patient with Post-CVA Hemiparesis and Pain. Neeman RL, Liederhouse JJ, Neeman M. *Can J Rehabil* 2(1), 1988 (in press).

Orthokinetic Orthoses: An Efficacy Study in Habilitation of a Person with Spastic Quadriplegia Secondary to Cerebral Palsy by Orthokinetics Treatment

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Sponsor: *Orthokinetics Research Foundation*

Purpose—This study investigated the efficacy of the application of orthokinetic orthoses to the upper extremities of a client in a sheltered workshop work activities program. The client had upper extremity incoordination secondary to spastic quadriplegia due to cerebral palsy.

Methodology and Results—The young adult male subject's upper extremity incoordination limited his production rate in work tasks to a marginal level prior to presenting for orthokinetics treatment. The treatments comprised a single-subject design time-series.

The client was a 22-year-old man with moderate spasticity and incoordination of the upper extremities due to cerebral palsy. He presented also with severe spasticity in the lower extremities, mental retardation, impaired vision, severe hearing loss, and lack of verbal communication. He had a pretreatment production rate of 7.6 percent of estimated industrial norm. He was treated by application of orthokinetic orthoses to both forearms and left wrist, in the time-series A1-B1-A2-C1-B2. A1 equaled the pretreatment negative control phase. B1 equaled the orthokinetics treatment phase, with an orthokinetic orthosis placed distally adjacent to the elbow, designed to facilitate wrist extension for functional grasp stabilization and finger extension for release of grasp. An additional orthokinetic orthosis on the left wrist was designed to provide additional stimuli for selective muscle facilitation and inhibition via the overlapping cutaneous mechanoreceptor fields of innervation. C1 equaled the placebo treatment phase, with the orthokinetic orthoses replaced by cuffs of plain elastic bandage.

The study was conducted double-blind, with the specifics of the orthokinetics and placebo treatments known only to the occupational therapist, but unknown to the client and to the production supervisor, who tallied the production rates throughout all phases of the time-series. Upon completed stabilization of baseline phase A1 (38 days), orthokinetics treatment phase B1 was started and continued for 15 days, until attainment of the preset interim habilitation goal of tripling the client's baseline production rate. It was followed by negative control phase A2, which comprised a post-treatment plateau (38 days); subsequent placebo treatment phase C1, which comprised a contiguous plateau (21 days) with that of the preceding negative control phase A2. The orthokinetics treatment replication phase B2 was then initiated, and continued (22 days) until attainment of the client's preset habilitation goal: average production rate in the sheltered workshop of 35 percent of estimated industrial norm. The results were subjected to statistical analysis to test for the presence of Lag 1 autocorrelation by Bartlett's test and found to be nonsignificant (absence of serial dependency). This permitted the application of the *parametric t* test, and *non-parametric* Mann-Whitney *U* test, both supporting the significance of the threefold rise in production rate during orthokinetics treatment phase B1; no reversals in negative and positive control phases A2 and C1; and renewed rise in orthokinetics treatment replication phase B2. All this supported the internal validity of orthokinetics treatment for the client with spastic quadriplegia, as well as clinical validity and utility of the orthokinetic orthotics application.

Future Plans—Future plans for the project include exploration of the clinical efficacy of orthokinetic orthoses applied to patients with paresis due to stroke and traumatic brain injury.

Publications Resulting from This Research

Application of Orthokinetic Orthoses in Habilitation of a Person with Upper Extremity Incoordination Secondary to Spastic Quadriplegia Due to Cerebral Palsy. Neeman RL, Neeman HI, Neeman M. *Can J Rehabil* 1(3):145-154, 1988.

Development of a Powered Orthosis for Lower Limbs

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Sponsor: *Office for Life Science Promotion of the Institute of Physical and Chemical Research, Agency of Science and Technology, Japanese Government*

Purpose—In order to restore an appropriate gait pattern, a powered orthosis is being developed for paralyzed lower limbs, that will support the patient's body and control lower limb movement. As a final goal, the powered orthosis will enable paraplegic patients to walk on level ground with a variable cadence, to stand and sit, and to go up and down a staircase by appropriate command.

Progress—Considering the results obtained experimentally through the preceding years, the second prototype was designed and constructed in 1986. Its main purpose was to have a powered orthosis for lower limbs of an appropriate size so that control methods explored in the past several years could be tested on paraplegic patients. The orthosis was fabricated in carbon-fiber reinforced plastic (C-FRP), and in thigh and femur parts, four electro-hydraulic actuators were incorporated. These actuators now have digital controls, in contrast with the first prototype which used an analog type. Each actuator is controlled by a single-board microcomputer, and all of these are totally controlled by a microcomputer. Sensory systems such as foot-switch sensors to detect plantar contact, optical encoder to measure relative joint angle, and posture sensor to measure torso inclination in sagittal and frontal planes are used to accomplish a stable powered walk. The orthosis itself weighs 19.5 kg, and its control wagon 68 kg, which should be moved with the powered walk. A powered orthosis will be realized using these two components.

Preliminary Results—After having checked the basic functions of the powered orthosis on a normal subject, it was tested on two paraplegics; both patients could walk with this powered orthosis grasping the rail of the wagon to balance the posture. This second version of the powered orthosis has sufficient torque for powered walk.

Future Plans—Since the first tests on paraplegics have been successful, the control methods developed on the first prototype will be applied to the second prototype to improve the function of the orthosis. As two orthoses have been constructed which are identical except for geometrical size, all the control methods will be thoroughly tested on normal subjects prior to the clinical tests.

Publications Resulting from This Research

Developpement d'une Orthese Active des Membres Inferieurs. Miyamoto H, Numao T, Ueda K, Sano A, Mori S, Sakurai Y, *Proceedings of the 11th Annual ICAART Conference*, Montreal, 92-93, 1988.

The Development, Manufacture and Clinical Evaluation of Modular Wrist, Hand and Finger Orthoses

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Sponsor: *Scottish Home and Health Department*

Purpose—Tayside Rehabilitation Engineering Services through its Orthotic Department has a wide experience manufacturing and fitting the bespoke wrist, hand, and finger orthoses to a wide range of patient categories and have evolved and refined a full range of both static and dynamic designs of orthoses. Recent work has included the modularizing where possible, of the components of these devices.

The aims of this project are: 1) to develop the existing prototype modular system of components to create an improved system capable of being easily and rapidly assembled to form complete functional wrist, hand, and finger orthoses; 2) prepare a prescription and fitting document for use with the system; 3) demonstrate the effectiveness of the modular system by clinical trials; and, transfer the system to a commercial manufacturer for future supply.

Progress—Nineteen types of modular interface components to fit the forearm (3 sizes), the palm of the hand (3 sizes), the complete hand including palm and fingers (3 sizes), and transverse bars to fit the dorsal surfaces of the phalanges have been constructed using vacuum forming techniques.

Dynamic components made from wire shaped into springs have been produced for the metacarpophalangeal (MCP) joints and the wrist joint. The characteristics required of these components have been determined by the use of instrumentation developed in the project.

Future Plans—Future plans include: 1) the continued development of rigid connectors to be used with the modular interface components to form static orthoses; 2) production of a prescription and fitting document based on an earlier booklet published by the developers; 3) protocol that had been produced for a multi-center clinical trial will commence later this year; and, 4) the manufacture of the complete system as the "Tayside Range" of orthoses by Hugh Steeper, Ltd.

Mechanics of Ankle-Foot Orthoses

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Sponsor: *University of Akron*

Purpose—Excess rotations at the ankle-foot complex present a major problem in the comprehensive rehabilitation of certain stroke patients with upper and lower motor lesions. These patients have uncontrolled muscle activity which may develop in to the "drop-foot" problem. Abnormal rotations also occur in the case of certain ligament injuries. Ankle-foot orthoses are generally prescribed to mitigate this problem. However, these orthoses have not been evaluated from a biomechanical view point. The purpose of the present investigation is to study the biomechanics of ankle-foot orthoses.

Progress—We have developed 2-dimensional finite element models of the ankle-foot-orthosis complex and studied various static and dynamic loading conditions. We compared stress and deformation patterns of the normal foot with those fitted with an orthosis.

In addition, we experimentally examined the strains developed in the orthosis in a walking cycle. Strain gauges were attached to polypropylene orthoses. The orthoses were fitted to normal test subjects and the strains were recorded during the gait cycle. The orthosis was held in place with a strap anterior to the calf, and a shoe which held the foot in the lower section. Principal strains were determined from three element Rosett gauges with assumed values for the material properties.

Preliminary Results—Peak stresses determined from both static and dynamic finite element models were similar in magnitude. Experimental results with strain gauges were consistent with the results of finite element model simulation. Slight geometric modifications of the orthosis were made to eliminate stresses at undesirable points. These design modifications allow functional plantar flexion, reduce instability at the subtalar joint, and facilitate heel-to-toe gait pattern.

Future Plans—The present simple 2-dimensional analyses demonstrate the feasibility of using finite element models for redesigning the ankle-foot orthoses. Further examination of dynamic conditions and more complex 3-dimensional dynamic finite element calculations are needed in order to be able to predict the total response of the ankle-foot-orthosis system.

We are developing 3-D finite element models of the ankle-foot-orthosis system. In addition, we propose to test-fit the orthoses to human subjects, and examine the effect of these orthoses on knee, ankle, and subtalar joints. Also, we plan to verify the results of the 3-D finite element model with experimental stress analysis of these orthoses. This would provide a comprehensive biomechanical understanding of the ankle-foot-orthosis systems.

Publications Resulting from This Research

One More Step in Redesigning the Ankle-Foot Orthotic. Lam PC, Downing M, Reddy NP. *SOMA*. 2(1):36-39,1987.

Stress Analysis of Ankle Foot Orthoses. Reddy NP, Yankee M, Lam PC. *Proceedings of 1987 American Society of Biomechanics Conference*. Davis, CA, 1987.

III. Total Joint Replacement and Other Orthopedic Implants

A. General

Bone Ingrowth and Remodeling with Porous Coated Implants

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A501-RA)*

Purpose—During the first grant period, our research group formulated a comprehensive theory which is consistent with many features of skeletal growth and development, maintenance, regeneration, and degeneration. The results of our previous investigations indicate that tissue stress histories play a major role in regulating the biology of skeletal tissues and that these influences are stronger and appear earlier in skeletal development than has been previously thought. The equations used to predict cartilage, bone, and mesenchymal tissue biology are similar to those that account for mechanical energy dissipation or the accumulation of fatigue damage in all materials. Our results may thus reflect fundamental characteristics of the transduction of mechanical energy to chemical energy in living organisms. The proposed research will further develop aspects of this theory. The context in which this work will be conducted is porous coated/bony ingrowth prosthetic replacement of the proximal femur and tibia. The end product of the research will be a consistent framework of computer analyses which can be applied to predict the biological events associated with initial ingrowth and subsequent bone remodeling. We anticipate that it will be possible to apply these approaches to the design and evaluation of any implant in any bone in the body.

Methodology—In the course of our investigations we will generate 3-D finite element models of the proximal femur and tibia. The loading history over some period (e.g., an "average" day) will be specified by a series of discrete load cases applied for a specific number of load cycles. The entire bone will initially be represented by a solid, homogeneous structure with a constant bone density. Using iterative bone remodeling techniques, we will remodel the bone computer models to create an internal distribution of bone density and morphology which conforms to our bone remodeling theory. The resulting prediction of bone density distributions will be compared to those measured from cadaveric specimens. Our theory and computer approaches may then be modified so that our predictions correlate better with normal bone anatomy.

The proximal tibia and femur models will then be altered to represent the initial implantation of various uncemented porous coated components. A thin layer of pluripotential tissue will be represented at the bone/prosthesis interface. The multiple-loading, stress history approach will then be applied and the differentiation of the interface tissue will be predicted. Using different stress history criteria, we will thus predict the extent and locations of bone ingrowth along the interfaces. Our criteria will be adjusted and varied parametrically to represent the types of results which have been observed by others in experimental animal studies and clinical retrievals. Subsequent bone remodeling around the prostheses will be calculated using the same algorithms which had been previously verified for the normal tibia and femur.

It is apparent that some design features may provide good initial fixation and encourage bone ingrowth yet lead to subsequent bone remodeling which is deleterious. We will be able to address this issue with our computer methods and thereby achieve a broad perspective of the overall implications of various design features. We anticipate that from the analyses that we perform, certain design features will begin to emerge which will suggest the evolution of cogent design principles for bony ingrowth total joint replacement.

The proposed work represents a melding of basic and applied research. Our theoretical approach to the regulation of skeletal tissue by mechanical stresses will be explored and refined while it is being applied to solve immediate design problems which have a direct clinical impact.

Implant Fixation by Post Insertion Pressurization of Polymethylmethacrylate

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A143-2RA)*

Purpose—Our purpose is to explore various methods by which the interface between polymethylmethacrylate (PMMA) and bone can be enhanced to achieve superior fixation between joint replacement implants and bone. Our theory is that sustained high pressure applied to the bone cement in a completely closed intramedullary system will result in an improvement of the mechanical parameters of the bone cement composite.

Progress—*An in vivo (time-zero) and in vitro comparison of sustained high pressure versus conventional hand-packed techniques.* In this study, a previously described cannulated canine knee replacement was used. A specifically designed testing jig was used to load just the bone cement interface. After loading 5 mm slices to failure, the ultimate load, stiffness and energy absorbed were calculated from the load deformation curve.

The findings were: 1) as compared to conventional hand packing, sustained high pressure significantly increased all of the mechanical parameters; 2) with both techniques, the values in the *in vitro* series were greater than the *in vivo* group. (This has been shown previously); and, 3) most importantly, the percentage increase in shear strength produced in the pressurized group versus the conventional technique was much greater *in vivo* than *in vitro*. This observation suggests that pressurization may compensate for the biomechanically detrimental effects of the *in vivo* environment.

Penetration and composite stiffness. Bone cement interface is strongest at the corticocancellous junction. To test this in an *in vitro* model, we compared the mechanical characteristics of the interface of the distal canine femur. The control group was prepared in the usual fashion; in the experimental group, all cancellous bone was removed to the corticocancellous junction. In both groups, sustained high pressure was utilized to inject the cement.

We found no difference in ultimate load between bone cement composites with cancellous bone only at the cortical junction as compared to more conventional specimens with much remaining cancellous bone. We attribute this to the depth of cement penetration achieved with this system. However, specimens with more cancellous bone had *less* stiffness and greater absorption of energy. Using the injection system described and conserving cancellous bone, it is possible to create a less stiff composite without losing composite strength.

Modes of failure. We looked at the failure patterns in 5 mm slices from both the femur and the tibia after insertion of a canine total knee.

A total of 232 slices were loaded to failure and examined with a binocular stereomicroscope. Six failure types were identified. The mean ultimate load for each type was determined and revealed a significant difference only between failure patterns one through four and types five and six.

Based on this data, the composites were divided into Mode I failure (varying degrees of failure at the bone cement interface) and Mode II failure (catastrophic failure of the interface, cement mantle and cortex).

When hand-packed and pressurized specimens were compared, there were significantly more Mode I failures in the hand-packed group, and significantly more Mode II failures in the pressurized group. Mode II failure had a greater ultimate load, shear strength, and energy absorbed than Mode I failure.

A comparison of intramedullary plugs used in total hip replacement. This *in vitro* study in human cadaver femurs evaluated the holding power, leakage and migration of bone, plus two commercially marketed polymeric plugs and PMMA plugs. Only plugs made of PMMA demonstrated an ability to not migrate, control the flow of cement, and maintain the pressure applied to the cement.

Greyhound alternative. Because of an controllable loss of mongrel canines for experimental use, we were forced to evaluate alternatives for the *in vivo* studies. An attempt was made to utilize greyhounds rejected for sporting purposes, but we had to abandon this effort because of problems with wound healing, skin breakdown and failure to thrive.

The goat alternative. We have subsequently found breeder-supplied goats a very satisfactory alternative. Although essentially untrainable and uncontrollable with respect to protection of the knee replacement that was done, our early experience has been quite satisfactory.

At present, we have a herd of 12 goats in which the total knee has been placed with sustained high pressurization of cement in six, and conventional cement technique in six. Sacrifice is planned at six months, at which time a time-zero procedure will be done on the opposite knee.

Publications Resulting from This Research

Regional Variation in Shear Strength of the Bone/PMMA Interface in the Human Femur. Bean DJ, Convery FR, Woo SL-Y, Lieber RL, *J Arthroplasty* 2(4):293-298, 1987.

Sustained Pressurization of PMMA Effects on Interfacial Shear Strength. Bean DJ, Hollis MJ, Woo SL-Y, Convery FR, *J Orthop Res* 6:580-584, 1988.

Effects of Treatment for Heterotopic Bone Formation on Biological Fixation

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Purpose—Ectopic ossification following total hip arthroplasty is a frequently reported complication, with occurrences ranging from 1 to 62 percent. The basic process of this phenomenon involves the laying down of osteoid matrix by osteogenic-competent mesenchymal cells. This is followed by crystal deposition and ultimate mineralization of the matrix. Considerable research has manifested controversial results regarding treatment modalities for the prevention of heterotopic bone formation. Recommendations for its prevention include the use of diphosphonates, indomethacin, and radiation therapy.

Diphosphonates have been shown to inhibit growth of hydroxyapatite crystals *in vitro,* and have been thought to prevent pathological calcification *in vivo.* Although widely-used clinically, two investigations have concluded that the use of diphosphonates is ineffective in preventing heterotopic bone formation.

In 1974 and 1977, studies were conducted to determine the effectiveness of indomethacin as a post-operative analgesic in the reduction of ectopic bone formation. Considerable reductions were observed. Further, it has been shown that osteoid and mineralized bone tissue formation were reduced in animals treated with indomethacin.

The therapeutic use of radiation to prevent or delay heterotopic ossification has also been presented. Two studies have reported the efficacy of treatments with 1,000 rads and 2,000 rads, respectively, in the prevention of heterotopic ossification after total hip arthroplasty. The mechanism by which prevention with radiation occurs, possibly involves the extreme radiosensitivity of the osteoblastic precursor cells which are prevented from multiplying and forming active osteoblasts.

The use of the fore-mentioned therapies in patients who are at risk for heterotopic ossification should be carefully considered, particularly in those cases where biological prosthetic fixation by bone growth into a porous-coated implant is planned. It is quite probable that bone growth into a porous-coated device will be significantly altered by either diphosphonates, indomethacin, or radiation therapy.

The purpose of this ongoing research is to elucidate biomechanical and histological effects of drugs and radiotherapy on bone growth into porous-coated Ti-6A1-4V alloy implants in canines. The study will include 50 adult beagles that will receive 4 bilateral transcortical porous-coated implants. The animals will be divided into 5 groups, 4 of which will undergo therapeutic treatments for heterotopic ossification. Group A will serve as the control group. Group B will undergo 2 weeks of pre-operative dosages of diphosphonates, followed by 4 weeks of post-operative treatments. Group C will undergo 4 weeks of post-operative diphosphonate therapy, with no pre-operative treatments. Group D will be treated for 4 weeks post-operatively with indomethacin. Group E will undergo radiation treatments to bilateral femora for 5 consecutive days post-operative, for a total dosage of 250 rads.

Implantation surgery will consist of the surgical placement of 4 transcortical porous-coated implants per femora. Each animal will undergo bilateral procedures. At 4, 8, 12, 24, and 48 weeks post-operative, the animals will be sacrificed. Bilateral femora will be harvested and prepared for push-out testing in order to determine the mechanical shear strength of the bone/implant interface. Some sections will remain intact for quantitative histologic evaluations of direct bone apposition and bone growth into the porous-coated implants.

The effect of each treatment modality will be evaluated in relation to implantation time, radiographic appearances, and *ex vivo* testing.

Implications—The results of this investigation will help elucidate the optimal treatment for ectopic ossification with the minimal hindrance to bone ingrowth and stability of implant fixation.

The Effect of Surgical Fit on the Biological and Mechanical Response to Porous Surfaced Implants

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Purpose—Ideally, a porous-surfaced implant relying on bone ingrowth fixation should make initial apposition with the surrounding bone. Unfortunately, this is not always achieved surgically at all locations, and a space between the implant and bone is present. This space may be the result of deficiencies in instrumentation design, implant design, or surgical technique. The gap may severely alter the type, amount, and rate at which tissue infiltrates the porous implant surface. Thus, the achievement of significant fixation strength may be delayed, or ultimate attachment strength affected.

Progress--A model to study the effect of such gaps on the quantity and quality of bone growth into porous-surfaced implants in both the cancellous and cortical bone regions has been developed, and will be used to study these parameters, including the interface attachment strength.

Implants will be constructed by threading varying diameter porous-coated titanium alloy discs on a central rod. The implants will be surgically placed bilaterally in the femoral intramedullary canals of 25 adult dogs. Uniform gap spaces of 0.0, 0.25, 0.5, 1.0 and 2.0 mm in width will be produced in both the cancellous and cortical bone regions of each femur. At intervals of 4, 8, 12, 24 and 52 weeks post-operatively, 5 animals will be sacrificed, and implant specimens will be mechanically tested to determine interface shear stiffness and strength of attachment. All specimens will be tested on a MTS closed-loop hydraulic system, using a ramp-type load below interface failure to first determine the interface shear stiffness. Subsequent loading to interface failure will then determine the ultimate strength. Intact specimens, as well as those mechanically tested, will then be processed using undecalcified techniques to produce histological and microradiographic sections for microscopic evaluation. The amount of bone growth within the porous surface, as well as the amount of bone filling the gaps, will be quantified on all specimens, using a computer-aided microscopic image analysis system. The study will yield differences in the biological and mechanical characteristics between varying gap spaces in both the cortical and cancellous regions as a function of time. Differences in the tissue ingrowth characteristics in the lateral, medial, anterior, and posterior locations in the cortical and cancellous regions will also be determined.

Determination of the Effects of Implant Interface Mechanics on Bone Remodeling

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Purpose—The relationship between bone remodeling and mechanical stress has vital implications with respect to interaction between orthopaedic implants and bone, especially with regard to loosening of joint replacement prostheses. The objective of this study is to gain knowledge about the biomechanical and physiological reactions of bone in relation to local mechanical stresses at the interface between bone and an orthopaedic implant.

Progress—First, we have established an *in vivo* model of a bone interface which can be investigated under known biomechanical conditions. In "loading" experiments, we start with control interfaces that form around special titanium screw implants (Branemark fixtures) in canine bones during a period of mechanically undisturbed healing. Then, these interfaces are mechanically challenged by programmed load waveforms applied to test implants *in vivo* by a MTS machine in load control. Second, in "micromotion" experiments the model is similar, except that smooth-surfaced titanium plugs in canine tibiae are displaced cyclically by known amounts with respect to interfacial bone using a MTS machine in stroke control; a special plate rigidly attached to the dog's bone serves as the displacement reference point.

Because we need accurate data on the presence or absence of bone-titanium "bonding," we are measuring interfacial shear strengths *in vivo*. These tests involve smooth-surfaced titanium plugs identical to those in the micromotion experiment, but which are implanted into canine femoral diaphyses for approximately 8 weeks and then pulled out axially *in vivo* via an MTS load frame. We are investigating two surface preparations: as-sterilized versus the radio-frequency-glow-discharge-treated (RFGDT). A unique feature of this experiment is that it is accomplished *in vivo* rather than on excised (dead) specimens.

Interfacial biomechanics are documented by finite element analyses and mechanical tests, and then compared with interfacial tissue reactions measured by histometric methods to reveal correlations between interfacial biomechanics and bone remodeling. Because joint replacements depend on secure and permanent fixation to bone, this project represents an unusual attempt to improve implant design by examining the effect of local interfacial biomechanics on interfacial bone.

Preliminary Results—*Loading Experiments.* The first series of experiments failed to reveal statistically significant histometric differences between loaded and control interfaces at 2 to 3 weeks after the end of loading, although there was a trend toward less bone-titanium apposition in loaded interfaces. To investigate these results, we have measured ultimate and fatigue strengths of screw-bone interfaces in samples of dead bone. It was concluded that a load amplitude of 300 N would represent a mechanically safe yet biologically significant challenge to bone at the interface in the next series of *in vivo* tests. We have successfully completed the *in vivo* loading phase (using 300 N) in a group of 6 dogs, and are now evaluating specimens at 5 weeks (4 implants) and 12 weeks (8 implants) post-loading.

Micromotion Experiments. The *in vivo* experiment has been designed to evaluate interfacial tissue reaction to 250 and 500 microns of micromotion (4 implants each), applied at 500 cycles per day (triangular waveform, 2 sec period), 2 days per week, for 4 weeks starting at 2 weeks post-implantation, with tissue evaluation at 8 weeks post-implantation.

Bonding Experiments. It is clear to us that at least two contributions to "interfacial shear strength" are possible: one due to mechanical interlocking between titanium (of known surface roughness) and a drilled hole in bone, and another due to interfacial physical/chemical bonding. Based on the above-noted mechanical tests of cylinders for the micromotion experiment, we are also gathering baseline data on the contribution due to interlocking. The implants are being prepared for the *in vivo* phase.

Future Plans/Implications—All phases of the loading, micromotion and bonding experiments are expected to be completed by Fall 1989.

Publications Resulting from This Research

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Histomorphometry of "Osseointegrated"-Type Interfaces Subjected to Different In Vivo Loading Protocols. Hipp JA, Brunski JB, Cochran GVB, *Proceedings of the 13th Annual Meeting of the Society for Biomaterials*, New York, 48, 1987.

The Influence of Force, Motion, and Related Quantities on the Response of Bone to Implants. Brunski JB, Chapter 2, 7-21, in *Non-Cemented Total Hip Arthroplasty*, R.H. Fitzgerald, Jr. (Ed.), New York: Raven Press, 1988.

Biomechanics and Histomorphometry of the Bone-Dental Implant Interface. Hipp JA, Brunski JB, Higuchi KW, *J Oral Implant* (in press).

Initial Stability of Orderly Oriented Wire Mesh Porous-Coated Implants

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Purpose—In an attempt to decrease the rate of aseptic loosening seen with cemented arthroplasty, porous implants have been developed. Ducheyne *et al.*, have developed a chemically pure (CP) porous surface constructed of an orderly oriented wire mesh. Its advantages include: 1) pore geometry within the optimal range of 100-400μm; 2) uniform pore structure; and, 3) materials continuity in coating, therefore excluding loosening of single particles. The purpose of this study was to compare bone ingrowth and fixation strength between a CP titanium (Ti) mesh surface and a double-layered CP Ti beaded surface.

Progress/Methodology—Rectangular plugs, 10 X 5 X 5 mm, were press-fit into the medial and lateral supracondylar region of both hind legs of 25 adult male beagles. The implants were coated on two sides with either Ti mesh or Ti beads. The mesh, a twill weave of 500μm thick wires, has a porosity of 50 percent. The Type 1 macro-pore averages 1,000μm in size, while the Type 2 and 3 pores (caused by the crossing of two wires) have an average pore size of 300μm. The Type 2 and 3 pores have an average area of $81 \text{ X } 10^{3} \mu m^{2}$. Beads of 550μm were double-layered to create a surface of 30 percent porosity and average pore size of 173μm. The average pore area for the beads was $51 \text{ X } 10^{3} \mu m^{2}$. Each hind leg received both types of implants according to a predetermined randomized order. Radiographs were taken pre- and post-operatively, and at sacrifice. Seven implants were tested immediately post-operatively for initial stability. The remaining dogs were sacrificed at 4, 8, and 12 weeks. Implants from one femur underwent mechanical pullout testing to determine ultimate strength. The contralateral femur was sagittally cut into 3 mm sections. These were fixed in formalin, dehydrated with ethanol, and embedded in polymethylmethacrylate (PMMA). Two hundred and fifty micron sections were cut on an Accutom Precision Saw, hand-ground to 40μm, and stained with Stevenel's blue, Van Giesen picro-fuschin, and Alizarin red S. Quantified histology was performed using a Zeiss Axiophot Light Microscope (LM) and an IBAS image analysis system. Paired t-tests were performed between groups.

Results—No implants became infected. Two dogs suffered intra-operative fractures and were replaced. On radiographic review, no lucencies were seen at the bone-substrate interface. The initial stability of the mesh and beads was 0.50 and 0.49 MPa respectively. Ultimate shear strength increased over time for both coatings. Mesh shear strengths were 2.0, 3.3, and 6.3 MPa for the 4, 8, and 12 week periods. Beaded implant shear strengths were 3.6, 4.9, and 7.6 MPa respectively. Bone ingrowth percentages increased over time. The mesh showed 21, 44, and 39 percent ingrowth, while the beads showed 30, 36, and 40 percent ingrowth over the 4-week intervals.

Implications—Both coatings studied showed increases in shear strength and bone ingrowth over time. The initial differences in shear strength resolved over time. This may be a function of pore geometry with bone ingrowth occurring at a faster rate for smaller pores. Once ingrowth is established into the larger pores of the mesh, equivalent stability is achieved. In this static model, the orderly oriented CP wire mesh has demonstrated potential utility as a bone ingrowth surface. Analysis using a loaded model is required.

B. Hip

Design Stress Analysis of Porous Ingrowth Hip Replacements

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Purpose—The objective of this study is to develop design concepts for porous ingrowth total hip replacements based upon a knowledge of the stress fields in the hip before and after joint arthroplasty. Attention will be paid to: 1) consistency between the calculated stress fields and bone trabecular morphology; 2) contact areas at the joint and implant interfaces; 3) initial stability of the implants under various loading conditions; 4) the types of stresses created at the porous ingrowth surfaces; and most importantly, 5) the manner in which bone may remodel in response to the change in bone stress caused by the implant.

Progress—Anatomical specimens were sectioned, X-rayed, and photographed to document geometry, distribution of bone density, and trabecular orientations. From these sections, 2-D finite element models of the acetabulum and femur were generated. Similar models with various porous implant components were also constructed. We developed a remodeling theory using a multi-load stress history approach which predicts the distribution of bone density in the natural and prosthetic femur. The technique is an iterative approach in which the bone is initially a solid, homogeneous structure with a constant bone density. The results are compared with normal bone anatomy and with findings from clinical studies.

Results—The finite element results of the acetabular region have provided new insights into how stresses are transmitted from the head of the femur to the pelvis. Simulating the implantation of an acetabular cup component, we reconfirmed some of the design principles that have been evolving concerning metal backing of this component. Our iterative bone remodeling theory has proven beneficial in trying to establish how the bone may redistribute itself after implantation of the prosthesis. Using this theory, we can recreate, on the computer, the natural bone morphology of the proximal femur. Starting with a solid block of bone, the remodeling routine predicted the development of a diaphyseal cortex and the dense compressive trabecular column through the head. The dense trabecular bone corresponding to the arcuate system in the lateral superior neck was also formed.

Application of our remodeling techniques to porous ingrowth components confirmed some of the experimental results reported by others. Computer examinations of the surface replacement component with the central peg predicted bone remodeling characterized by dense deposition of bone around the peg. Our remodeling technique also indicates that our epiphyseal replacement prosthesis may be well-designed to avoid adverse remodeling influences after implantation. We have made prototype implants with this new design and plan some experimental implantations.

Future Plan—We intend to further develop our remodeling theory and improve the computer codes implementing this theory. More extensive examinations of bone remodeling around prosthetic components will be conducted in 2-dimensional and 3-dimensional analyses with the inclusion of rate remodeling. We propose to perform an *in vivo* animal study to verify the theoretical model. On the basis of the results, we will refine our design of both the prosthesis and the surgical instrumentation and then decide whether further animal studies are warranted.

Publications Resulting from This Research

Contact Finite Element Stress Analysis of Porous Ingrowth Acetabular Cup Implantation, Ingrowth, and Loosening. Rappaport DJ, Carter DR, Schurman DJ, *J Orthop Res* 5:548-561, 1987.

Relation of Coxarthrosis to Stresses and Morphogenesis: A Finite Element Study. Carter DR, Rappaport DJ, Fyhrie DP, Schurman DJ, *Acta Orthop Scand* 58, 1987.

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Effects of Ingrowth, Geometry, and Material on Stress Transfer Under Porous Coated Hip Surface Replacements. Fyhrie DP, Carter DR, Schurman DJ, *J Orthop Res* 6:425-433, 1988.

Application of a Bone Remodeling Theory to Femoral and Tibial Prosthetic Components. Orr TE, Beaupre GS, Fyhrie DP, Schurman DJ, Carter DR, *Transactions of the 34th Annual Meeting of the Orthopaedic Research Society,* 13:100, 1988.

Femoral Head Apparent Density Predicted from Bone Stresses. Fyhrie DP, Carter DR, *J Biomech* (in press).

Quantitative Analysis of Total Hip Arthroplasty on Stress and Strain

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Purpose—New acetabular cup and femoral stem designs and implantation techniques have been developed to improve the overall performance of total hip arthroplasty. Little quantified experimental information has been available concerning the effect of implantation of these devices on human pelvis stress and strain as compared to the natural hip joint. Using strain gauge instrumentation, this long-term investigation has quantified pelvic strain changes following implantation of various acetabular cup designs. The basic premise has been that bone strain changes may be predictive of the long term success or failure of the arthroplasty.

Progress—Following initial work which led to the development of an automated computerized data acquisition system and customized loading fixtures, assessment of various implantation techniques and prosthesis designs on pelvic wall strains during simulation of single limb stance phase were recorded. Techniques including the use of pilot holes, reaming of subchondral plate, cement restricters, and spacers for insuring a uniform cement mantle were evaluated.

Results—Results indicated that pilot holes and substantial reaming leads to large increases in pelvic strain per unit applied load. Uniform cementation leads to minimal changes in pelvic strain when the compliance of the component itself is appropriate. Evaluation of cup designs as they relate to implant compliance and their effect on pelvic strain was also determined.

Results also indicate that low compliance standard polyethylene components tend to increase pelvic strain considerably while thick cobalt-chrome (CoCr) metal-backed components lead to stress protection. Titanium metal-backed prostheses and thin CoCr metal-backed components with spacers led to intermediate marginal strain increases. The evaluation of non-cemented screw-in CoCr implants showed that while their strain change/unit applied load behavior was somewhat akin to the stress protection thicker CoCr afforded, considerable undesirable initial hoop stresses were generated during insertion. Additionally, new designs of metal-backed porous-coated components have been evaluated, and they confirm that strain changes in the pelvis may be controlled with the control of implant compliance and insertion methodology.

Evaluation of press-fit non-cemented femoral components has begun, using a newly-developed holographic interferometry technique. Interferograms of cadaver femurs under simulated physiological loading conditions were generated. After implantation of cementless prostheses with different qualities of fit, interferograms were repeated with different loading levels. Discontinuities in slope were found at the distal tip of the prosthesis, thus areas of increased strain at the distal tip of the prosthesis are present.

Future Plans/Implications—These initial investigations have shown that holographic interferometry is a useful non-contact method for biomechanical analysis of out-of-plane motion of orthopedic implantations, if careful technique is carried out. Accuracy of fringe location was shown to be of paramount importance (errors induced compounded when further mathematical differentiation was carried out). Simplified plexiglass models have been created to ascertain the system accuracy, and will be tested in the same manner as the cadaveric femora. The resulting displacement fringes will be compared to those theoretically predicted by finite element method (FEM) techniques. Additionally, speckle interferometry and shearography will be implemented to analyze "in-plane" motion, while shearography will provide optical differentiation of displacement to obtain strain values directly from the specklegram. The accuracy of these newer techniques will also be compared to FEM results. Following these "calibration" procedures, a series of press-fit porous-coated devices with varying classes of fit will be evaluated for explanation of the performance of these devices *in vivo*.

Optimized Surface Bonding and Stiffness of Femoral Endoprostheses

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Purpose—The long-term objective of this investigation is to develop a safe and longer-lasting prosthetic total hip replacement. The short-term objective is to determine the optimal surface characteristics and material properties for the femoral component. The specific short-term objectives of this investigation are: 1) To investigate the following design variables for femoral components using 3-dimensional finite element models: a) the stem shape, including a conventional straight stem Moore-type endoprosthesis and a modern contour-fitting design; b) a collar for calcar contact; c) the surface regions for bone-prosthesis bonding; and, d) the anisotropic elastic moduli for the prosthesis material. 2) To generate an idealized macroscopic finite element model of a prosthetic stem, with and without a collar for calcar contact, in a femoral diaphysis. The 2-dimensional plane stress model, using the equivalent thickness method with spanning elements, will include nonlinear contact with Coulomb friction at the bone-prosthesis interface. This model will be used to determine the relationship between the friction coefficient and micromotion at this interface.

Methodology—We will start with the mesh of an intact femur that was previously developed. This femur was carefully selected from a large geometric database. Four different prosthesis designs will be investigated using the combination of two stem geometries, each with and without a collar. The critical stresses in the supporting bone and at the bone-prosthesis interface will be examined as a function of the regional surface bonding and the material properties of the prosthesis for each of the four geometries. The predicted stresses will also be evaluated by direct point-by-point comparison of the stresses surrounding the endoprosthesis to the stresses in the intact femur.

The innovative aspects of this proposed investigation include the application of optimization techniques to the distribution of surface bonding and prosthesis material properties, the direct point-by-point comparison of stresses around a prosthesis to the stresses in an intact bone, and the application of nonlinear interfaces with Coulomb friction to the modeling of bone-prosthesis systems.

Skeletal Aging and Disease in Failure of Hip Surface Replacement

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Purpose—The objectives of this project are to determine the causes of early loosening in surface replacement hip arthroplasty (SRHA), and the relationship between these causes and skeletal aging and disease. Possible causes include: 1) poor initial fixation due to inadequate operative technique and instrumentation; 2) bone necrosis secondary to disruption of the blood supply; 3) inadequate (age/disease-related) initial bone strength; and, 4) bone remodeling due to stress redistribution, related either to prosthesis design or to processes of aging and disease. Data obtained from this study will be used to determine the viability of SRHA and, if possible, to design improved components and techniques.

Results—In a blood flow study of eight dogs, the flow to the femoral heads was predetermined two days prior to capsulectomy. Eight hips were capsulectomized and the bilateral hip was undisturbed. A 35 to 70 percent reduction in blood flow was seen using a technetium-99m HDO- and MDP-based bone scanning and scintillation counting method. Capsulectomy is an unavoidable procedure in surface replacement: these results suggest a compromise in blood flow to the femoral head.

Quantitative radioactive mapping (counts/gram) of the capsulectomized femoral heads revealed regional changes associated with loss of blood supply. There was no specific pattern to the bone necrosis, which suggested that prosthetic designs could not be developed to allow for adequate fixation of the femoral component to the bone.

Three-dimensional mapping of the mechanical strength of the femoral head is complete. The work determined that 3-dimensional mapping of the local cancellous bone was feasible and helpful in determining the differences between osteoarthritic and normal cancellous bone in femoral heads. The ultimate strength was higher in osteoarthritic bone compared to normal, while the yield point and stiffness of diseased bone to withstand the cyclic loading was lower. This is a compromise which contributes to clinical failures unrelated to prosthetic design or surgical approach.

From this came the idea to develop an intraoperative, hand-held device to determine the bone quality of cancellous bone during total joint replacement arthroplasty, that may help the surgeon determine if the bone quality of the patient is adequate for uncemented devices.

Two predominant metals used in joint replacement are titanium and cobalt chrome. Test pellets of titanium alloy with porous coating using two different pore sizes (300-450 μm and 500-800 μm) were tested in human and canine cancellous bone under load-bearing conditions to determine if the cancellous bone might better affix to the larger pore size. Also, an osteoconductive substance, hydroxylapatite (HA) was plasma-sprayed onto the 450-800 μm porous-coated titanium specimens to determine if the known osteoconductive capabilities of HA-enhanced skeletal attachment. Porous-coated cobalt chrome test pellets, with an average pore size of 425 μm, were tested to determine any ingrowth changes associated with material changes.

Conclusions were that cobalt chrome is a disadvantaged material for use in bone ingrowth prosthetic devices. The larger pore size (450-800 μm) titanium alloy material was an advantage over the smaller. One of the significant findings was that the canine model did not discriminate the differences in prosthetic material and is a suspect model for humans.

The quest for improved analysis of remodeling has led to an involvement with backscattered electron (BSE) imaging using the scanning electron microscope. Automated imaging is being developed to allow high resolution images to be used to assess mineralization changes in bone associated with aging and therapeutic treatments. This will contribute to the diagnosis of related bone and joint diseases.

An implant donor program has been designed to analyze asymptomatic implants post-mortem. Information obtained will help us to understand the long-term effect of implants and assist with improvements. Our goal is to be a national center for implant analysis.

Future Plans/Implications—Principal activities will include continued collection and processing of specimens and analysis of data for relationships between prosthetic design and bone remodeling. Whenever possible, SRHA patients who suffer from failed prostheses and are scheduled for hip replacement surgery, will undergo both histological and scanning analysis.

Publications Resulting from This Research

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C. Knee

Design Concepts for a Porous-Ingrowth, Prosthetic Tibial Component

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A333-RA)*

Purpose—The objective of this study is to develop design concepts for a porous-coated/bony-ingrowth prosthetic tibial component.

Progress—We have utilized a combined experimental and computational approach to study both conventional and new knee implant designs. The analysis of conventional designs has allowed us to identify the primary design features which are responsible for the shortcomings which are observed clinically. We have examined two primary design parameters; tray geometry and fixation peg shape and size.

The mathematical models are based upon the finite element technique. These models provide information about the change in the distribution of bone density caused by implantation of the prosthetic component. Linear models have been used to simulate the firmly attached prosthesis and nonlinear, friction interface models can be used to study the newly-implanted prosthesis.

For all models, the predicted stress distributions for each implant design will be compared with the trabecular morphology from cadaver tibiae to determine which designs will likely result in the least amount of remodeling.

For the experimental study, a urethane foam was used to simulate trabecular bone. The foam was designed to have material properties comparable to trabecular bone. Various fixation pegs machined from aluminum and steel have been tested to determine their resistance to shear motion and its relationship to peg shape, size, and number.

Results—Linear, 2-dimensional, equivalent-thickness models in both the frontal and sagittal planes have been developed for the natural tibia and for a variety of conventional and new tibial component designs. These models have shown that large central posts give rise to greatly altered stress distributions. New designs based upon the bony architecture of the epiphyseal scar lead to more benign, near-normal distributions. Iterative remodeling models predict that the altered stress states engendered by conventional tibial prostheses will lead to excessive bone remodeling, eventually leading to the loss of peripheral bony support concomitant with a densification at the post/peg tips.

The experimental program has shown that smaller fixation pegs can be used effectively to provide the same degree of stability as larger posts with much less bone sacrificed. This will result in less stress shielding and it will improve the chances for success should revision surgery be necessary.

Future Plans/Implications—The experimental phase of our program is proceeding with the testing of various fixation pegs in cadaver tibiae. With this testing, peg placement on the resection plane will be addressed. Paired tibiae will be used. Mechanical similarity of the paired tibiae will be assessed using dual energy computerized tomography. Strength testing will then be performed on one tibia, and stability and micromotion testing will be done on the contralateral bone.

For the mathematical modeling phase of the program, a new, rate-dependent, surface-area-based bone remodeling technique is being developed which will be used to predict the time course of density changes. Information on rate remodeling constants is being collected from the literature. If the literature values prove unreliable or inadequate, an experimental animal model may be necessary to define typical rate constants. Once the rate constants have been satisfactorily defined, the rate-dependent remodeling approach will be applied to 3-dimensional models of the prosthetic tibia.

Publications Resulting from This Research

Applications of a Bone Remodeling Theory in the Design of Bony Ingrowth Prosthetic Components (Abstract). Carter DR, Fyhrie DP, Orr TE, Vasu R, Beaupre GS, Schurman DJ, *Proceedings of the Third Biomaterials Symposium*, Goettingen, Germany, June, 1987.

Advances in Total Joint Replacement. Beaupre GS, Carter DR, *VA R&D Newsletter*, February, 1987.

Applications of a Bone Remodeling Theory to Femoral and Tibial Prosthetic Components (Abstract). Orr TE, Beaupre GS, Fyhrie DP, Schurman DJ, Carter DR, *Trans Orthop Res Soc* 13:100, 1988.

All-Plastic Total Knee Replacement

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A217-RA)*

Purpose—The objective of this project is to develop a total knee replacement prosthesis made entirely from a polymeric (reinforced) material. The hypothesis is that the lower modulus of the polymeric material will allow the fabrication of more flexible components that will lead to a more normal remodeling of bone adjacent to the prosthesis.

Methodology—An apparatus to evaluate the tribiological performance of candidate polymeric materials has been constructed. The coefficient of friction and wear-rate of various combinations of polymer-on-polymer articulation will be evaluated. In addition, the morphology and size distribution of wear particles will be determined.

A second aspect of this investigation has been to construct other apparatus to evaluate the morphology and size of particles generated when candidate polymeric materials are abraded against bone, as can happen with cementless prostheses. Prototype polymeric knee prostheses have been implanted in several dogs in order to begin to evaluate the histological response to the biomaterials and devices.

Ongoing studies are evaluating candidate polymeric materials, and carbon fiber reinforced polymeric composites in the two wear-test apparatus. Additional prototyped knee replacement prostheses will be implanted in dogs to continue the histological evaluation of the tissue response to these implants.

The Cementless Application for the Intermedics Natural-Knee® with Cancellous Structured Titanium™ (CSTi)

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Sponsor: *Intermedics Orthopedics, Inc.*

Purpose—Indications for the use of the Natural-Knee® with CSTi™ are: Patient conditions of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies; correctable valgus-varus deformity and moderate flexion contracture; and, patient conditions of failed previous surgery where pain, deformity, or dysfunction persists.

Progress—Twelve clinical investigators have entered patients into the study since September, 1987. One hundred and eighty-one devices have been implanted as of September, 1988. Data from 167 implants have been analyzed for presentation in a full report. The mean age of the study group is 69 years; the majority of patients in the study (145) had the diagnosis of osteoarthritis.

Preliminary Results—The effectiveness of the Natural-Knee® is indicated by the preliminary results of clinical evaluations (modified Hospital for Special Surgery rating scale: MHSS) preoperatively and at the 3- and 6-month evaluation visits. No patients have reached their 1-year evaluation visits to date (September, 1988). Of the 167 implants, data were available to calculate the total mean MHHS for 152 implants at the preoperative visit, 88 at the 3-month visit, and 18 at the 6-month visit.

Future Plans—Completion of 350 implants is projected by February, 1989. Adequate 2-year data on a minimum of 100 patients is anticipated by 1990.

D. Spinal

Dynamic Biomechanics of Spinal Implants

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B365-2R)*

Purpose—The overall objective of this study has been to establish a comparative database for cyclic, nondestructive, multidirectional *in vitro* testing of Harrington, Drummond and Luque spinal implants.

This information will aid in the development of safer and more biomechanically-sound instrumentation systems.

Methodology—During the 1987-1988 year, Harrington, Drummond and Luque spinal implants attached to swine spines were tested in a pneumatic-powered machine designed for multidirectional cyclic testing. Spine segments of 13 vertebrae from T7-L4 were used. Vertebrae at each end of the spine were encased in acrylic within aluminum cups for attachment to the testing frame. The spines were cycled at 1 cycle per second. The maximum excursion of the compression cylinder was set at 1.3 cm. The torsional cylinder allowed 15 degrees of clockwise and counterclockwise angular displacement. Each spine was tested without instrumentation (control), then with a single Harrington-Moe distraction rod, Drummond rods, and paired Luque rods. Spines were preconditioned for each of 6 testing modes to allow for equilibration. Compression, torsion, combined compression, and torsion simultaneously applied by independent pneumatic cylinders, as well as off-axis compression, off-axis torsion, and off-axis compression-torsion, were the 6 modes tested. Radiographs were taken prior to testing, after applying instrumentation, and at the completion of testing. Nine points located at 3 orthogonal triaxial reference devices positioned at the upper, middle, and lower segments of the spine were digitized using photographs taken from video tapes. The digitized points were analyzed using a computer program especially designed for the project and the data subjected to statistical analysis to ascertain the relative differences in linear and angular displacement of the implants during each of the 6 testing modes.

An anterior spinal implant was designed and several prototypes have been manufactured for testing. Cyclic testing, using methodology as described for the posterior implants, with appropriate modifications, is being done. This implant is a cylinder, 20 mm in length and 8 mm in diameter, containing a spring mechanism with plungers held in a retracted position until implantation. A diskectomy was performed, the end-plates between the vertebrae were removed, and a trephine was used to prepare for bone graft placement. Holes 4 mm in diameter were drilled within the centers of adjacent diskectomized vertebrae for insertion of the anterior implant. The spines were cycled 1 cycle per second through each of the 6 testing modes. Radiographs were made before and after testing.

Results—Cyclic multidirectional testing of Harrington, Luque and Drummond systems did not result in either implant fatigue, failure of the spines, or significant destructive interactions during the 28,000 cycles imposed on each of the 11 spines. Slight fretting and accumulation of metallic wear debris was noted between the rod and wire interfaces. Although the Harrington hooks were noted to rotate during cycling within their laminal attachment sites, there was no hook dislodgement or cut-out. Although not statistically significant, the Drummond and Luque implants tended to be more stable in compression, off-axis compression, and off-axis compression-torsion than the Harrington.

Cyclic multidirectional testing of the prototype anterior implant has recently commenced and data are not complete. Implant stability *without* evidence of loosening or erosion at the fixation sites has been observed for the prototype implants tested to date.

Future Plans—We are encouraged with the current design and performance of the prototypes which are being modified for *in vitro* and animal model *in vivo* testing. A posterior implant system consisting of paired semiflexible graphite fiber reinforced composite rods attached to the pedicles and facets by anchoring posts capable of bio-ingrowth response is in the design stages.

IV. Spinal Cord Injury

A. General

Effects of Electrical Stimulation on Chronic Spinal Spastic Bladder

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Purpose—Spastic bladder contractions in the spinal cord injured (SCI) patient result in incontinence, and in conjunction with high urethral resistance often result in high bladder pressure associated with renal morbidity. These unwanted bladder contractions seem to result from loss of inhibition from higher brain centers following injury. This project's goal is to learn more about the mechanism of bladder dysfunction following spinal trauma, and to use this knowledge to develop ways to manage urinary functions following injury. These observations complement our studies in which we are focusing on clinical trials for bladder management following SCI.

Progress—One spinal cat (T1) was instrumented with four epidural electrodes (Pisces Quad, Medtronic) implanted adjacent to sacral nerves using a modified percutaneous procedure. The animal was managed twice a day for 8 weeks with manual bladder expression (Crede's procedure) or sacral stimulation using either the epidural electrodes or sacral surface electrodes. The cat received daily nursing care and remained in excellent health throughout the experiment in accordance with American Association for Accreditation of Laboratory Animal Care (AAALAC) guidelines.

In the early spinal cat, 1-2 weeks postinjury, urodynamic responses to sacral stimulation, bladder filling, and Crede's procedure were noted. Bladder filling did not induce bladder contraction or voiding. Sacral stimulation with either implanted or surface sacral electrodes induced bladder contractions less than 40 mmHg with no voiding. Crede's procedure induced minimal voiding which was interrupted by exaggerated urethral closure activity. This urethral reflex activity can best be described as a urethral emptying reflex (UER) where closure of the urethra during voiding empties the urethra. This UER was indicated by pelvic floor and anal contractions as well as more peripheral responses such as penile erection and leg flexion. Fluoroscopy confirmed the pelvic floor responses by showing closure of the urethral sphincter interrupting voiding.

In the late spinal cat, 3-8 weeks postinjury, the urodynamic pattern changed, but the UER was still present. Bladder filling produced spontaneous bladder contractions with voiding. The UER interrupted the voiding stream. Voiding responses to sacral stimulation were improved, but still left high residual urine. However, the bladder could be easily emptied by Crede's procedure. The UER, as described in the chronic spinal male cat, may be a mechanism contributing to the high urethral resistance (sphincter dyssynergia) seen in SCI patients.

Inhibition of bladder contractions in response to bladder filling was also studied during the late period. Attempts were made to identify stimulating currents for bladder inhibition at 6 and 60 pulses per second. Inhibition was not seen with a variety of stimulating techniques. These included sacral stimulation with implanted or surface electrodes, pelvic floor stimulation with needle electrodes, or nerve stimulation in the leg. This lack of inhibitory effects may have resulted from a low threshold for inducing bladder contractions and leg spasms. On the other hand, inhibition was seen with perineum cutaneous procedures of pinching or injecting bradykinin. Since these procedures are associated with stimulating pain receptors, we suggest that stimulation of pain afferents may be effective in bladder inhibitory treatments.

Factors Influencing Joint Compliance and Reflex Mechanisms in Spinal Cord Injury

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Purpose—The normal pattern of motor control is greatly altered by spinal cord injury (SCI). Much of the characterization of reflex activity in individuals with SCI comes from studying electromyographic responses to peripheral nerve stimulation, not to passive or active limb movement where joint compliances can be measured. While controlled passive movements can be achieved with torque motors, active movements in some of these individuals can be initiated with surface electrical stimulation. Restrengthening of paralyzed muscles by such stimulation also might alter compliance and reflex activity.

The following questions will be addressed in this project. Can joint compliance and spinal cord and supraspinal reflex activity be reliably measured in individuals with SCI? How does this activity change over the time since injury? Do joint rotations yield a more complete and reliable characterization of the peripheral motor control loop than do measurements of H-reflex changes? Are the compliances and reflexes different when the muscles are being activated by electrical stimulation? Does electrical muscle reconditioning alter compliance and reflex activity?

The research will be based on the following hypotheses: 1) Any treatment or pathological course that alters a muscle's capability for volitional movement, response to electrical stimulation, or reflex excitability will be reflected in appropriate measures of joint compliance and reflex activation that are obtained by measuring mechanical and electromyographic responses to mechanical perturbations of the joint. 2) In adult-onset SCI, joint compliances and reflexes will change in a characteristic fashion that depends on the level and completeness of the injury: (a) during the evolvement of SCI (i.e., during the first 6-months post-injury); (b) following 1-week controlled removal of anti-spasmodic medications in individuals with chronic (1-year post) SCI; and, (c) following a 4-week period of electrical muscle reconditioning. 3) The changes in joint compliance will correlate with changes in residual supraspinal influences since measurements of joint torque and angle should be more physiologically appropriate.

Methodology—We will measure the time pattern of joint compliance at elbow, ankle, and knee, using step and sinusoidal mechanical perturbations of limb position; EMGs and stretch reflexes of appropriate muscles; and H-reflex at soleus. Limb position will be set passively or by volitional effort or electrical stimulation and results compared. We will check for supraspinal influences. The populations to be studied are: 1) neurologically-intact; 2) motor-impaired due to SCI; 3) motor paralyzed-tonic; and 4) motor paralyzed-flaccid. Intervention: If less than 6-months post-injury, we will monitor changes in measures over time for groups 2 and 3 above and compare with sequelae. If greater than 6-months post-injury, we will measure and then attempt to restrengthen paralyzed muscles of groups 2 and 3 above, then remeasure. We will compare subject responses while receiving long-standing clinically prescribed anti-spasmodic medications to that obtained on drug holiday. We will use the neurologically-intact subjects and the flaccid-paralyzed subjects as controls.

The project will cover a 3-year period. During the first year, we will concentrate on ankle joint in recently-injured SCI patients (4 to 6 "complete," 4 to 6 "incomplete"), compare joint compliance, EMGs, mechanically and electrically (H-reflex) induced reflexes, supraspinal influences, and volitional and electrically-stimulated muscle strength. We will trace changes in these comparisons as the rehabilitation of the individual progresses. Just before discharge, subjects will be put on 1-week drug holiday, then remeasured. In the second year, we will continue these activities, but will also include knee and elbow joints (compared cervical with thoracic lesions). In the third year, we will test the effect that a 4-week program of electrically induced exercise has on these measures for patients who are more than 6-months post-injury.

Electric Field Distribution in the Injured Spinal Cord

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B423-RA)*

Purpose—Properly configured, externally applied electric fields aid in guiding the regeneration of central nervous system axons. If the effect of electricity upon regeneration is to be properly evaluated, the distribution of electrical current and potential in the tissue must be determined for the electrode configurations and electrical parameters which are suggested to produce beneficial effects. Because many studies have been conducted using *in vitro* preparations, it is necessary to establish the geometrical factors which determine the magnitude and direction of current in intact spinal cords to insure comparability of the results.

This study proposes to evaluate the biophysical and neuroanatomical aspects of electrically-facilitated neural regrowth in experimental animals. Initial studies are designed to measure the current distribution secondary to applied electrical potentials from implanted electrodes over the spinal cord in cats. The data generated from these electrical measurements will be used to direct experiments to evaluate neural regeneration in the chronic animals. The degree of observed axonal regrowth will be correlated with measured electric field intensities.

The objectives of this project are: 1) to measure the electric field distribution in the spinal cord of the cats before and after spinal cord injury; 2) to measure the electric fields in the spinal cord resulting from applied current from implanted electrodes; 3) to correlate the degree of axonal growth due to electrical stimulation with electrical field distribution; and, 4) to implement a standard measure of comparison, i.e., current density measurements, to evaluate electrical stimulation techniques with different electrode configurations and stimulation parameters.

The results of these studies will permit 3-dimensional plots of the potential distribution due to the injury currents, and the potential distribution following the application of therapeutic currents. This will enable investigators using electric currents for regeneration to determine the magnitude and orientation of currents actually used *in vivo*.

Progress—The study tested the effects of electrical currents of small magnitude on the injured spinal cord fibers in cats. Five female cats weighing 2–2.5 kg were anesthetized with intramuscular injections of ketamine and xylazine. Using an operating microscope, a laminectomy was performed under sterile conditions at T8, T9 and T10. The dura mater was incised, and the spinal cord was completely transected at the level of T9. In three animals, a galvanotropic neural device (Traxon™) was implanted with the anode 1 cm rostral to the lesion and the cathode 1 cm caudal to the lesion delivering 14μA DC epidurally to the spinal cord. The control group consisted of two unstimulated, but spinal cord transected cats.

A modified Tarlov's scale was used for neurological motor testing of these animals. A 0-5 scale was utilized.

Results—All animals had muscle tone present. However, one of the two control spinal cats showed atrophy of hindlimb muscle. Two out of three cats which had received electrical stimulation for 20 weeks showed some weight support on their hindlimbs. These results correlated with the electrophysiological recordings. All animals showed good responses when the stimulation and recording were both either above or below the lesion. The responses were absent in the control group when stimulation and recording was done across the lesion. Two of the animals in the electrically-stimulated group showed consistent responses beginning at 3 msec and peak at 4 msec. These results will also be evaluated in the light of the histological assessment.

Future Plans—Different electrode configuration and stimulation parameters will be used to look into the optimal response to treatment.

Publications Resulting from This Research

Injury Potential Distribution in Cat Spinal Cord. Myklebust JB, Khan T, Swiontek T, *8th Annual Meeting Bioelectrical Repair and Growth Society*, Washington, DC, 1988.

The Corticospinal System

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Sponsors: *VA Rehabilitation Research and Development Service (Project #B389-RA); National Institutes of Health; Eastern Paralyzed Veterans Association*

Purpose—The purpose of our studies is to identify corticospinal systems which may be important in the recovery of function following spinal cord and cortical injuries.

Progress—The corticospinal tract in macaques contains an ipsilateral component which does not cross at the pyramidal decussation. A portion of the ipsilateral pathway travels in the dorsolateral funiculus along with the contralateral component of the tract. Clinical and experimental evidence suggest that the recovery of motor function that follows damage to contralateral motor pathways depends in part on the integrity of this ipsilateral pathway. This year we have focused our studies on defining the origin of corticospinal projections from the ipsilateral hemisphere using retrograde transport of horseradish peroxidase (HRP).

Results—HRP was placed in the dorsolateral funiculus at the second cervical segment in monkeys. We found that all of the cortical areas which project via the contralateral corticospinal tract also contribute to the ipsilateral corticospinal tract. This includes five cortical areas in the frontal lobe (e.g., the primary motor cortex, the supplementary motor area, the arcuate premotor area, and two areas in the cingulate sulcus) and five regions in the parietal lobe (e.g., the primary somatosensory cortex, the secondary somatosensory cortex, area 7b, granular insular cortex, and several portions of area 5). In each cortical area, the size range for cells which contribute to the ipsilateral tract is the same as that for cells which contribute to the contralateral tract. A density analysis indicates that proportionally more of the ipsilateral projection originates from the frontal lobe than originates from the parietal lobe.

Within the ipsilateral primary motor cortex, substantial numbers of corticospinal neurons were found in regions of forelimb representation located on the crest of the precentral gyrus and in the rostral bank of the central sulcus. Thus, projections to the ipsilateral corticospinal tract include cortical regions involved in the control of distal limb movements. Furthermore, some of these projections originate from the largest cells in the ipsilateral primary motor cortex.

Future Plans/Implications—Our observations indicate that even following damage to the corticospinal pathways of the contralateral hemisphere, substantial projections to the spinal cord remain from the ipsilateral hemisphere. In addition, our results indicate that the densest component of the ipsilateral pathways originates from motor areas of the frontal lobe. Finally, our observations indicate that the ipsilateral pathways originate from regions of primary motor cortex that are concerned with the control of both distal and proximal limb movements. Taken together, these results offer the possibility that ipsilateral pathways play a substantial role in the recovery of motor function which occurs following damage to contralateral systems.

Publications Resulting from This Research

Organization of Corticospinal Projections in the Macaque: Extent of Projections from the Parietal Lobe. Dum RP, Strick PL, *Soc Neurosci Abs* 13, 1987.

Origin of Corticospinal Projections to the Ipsilateral Spinal Cord. Hutchins KD, Strick PL, *Soc Neurosci Abs* 13, 1987.

Corticospinal Projections from the Medial Wall of the Hemisphere. Hutchins KD, Martino AM, Strick PL, *Exp Brain Res* 71:667-672, 1988.

Anatomical Organization of Multiple Motor Areas in the Frontal Lobe: Implications for Recovery of Function. Strick PL, *Advances in Neurology,* Vol. 47, S.G. Waxman (Ed.), Raven Press: New York, 293-312, 1988.

Performance Testing of Devices and Procedures Applied to Acute Spinal Injury Patients

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Sponsor: *VA Rehabilitation Research and Development Center Core Funds*

Purpose—Apparatus for moving and physically supporting acute spinal cord injury patients must stabilize the damaged vertebral column against largely unknown levels of acceleration and vibration. Equipment testing is commonly by static X-ray, whereas the actual use environment is one of dynamic mechanical input. Failure of stabilization may cause additional trauma to the spinal cord.

Progress—We have tested patient support equipment such as backboards and litters, invasive (skeletal tongs and halos) and noninvasive ("TACIT" device) traction interfaces, and cervical collars in both laboratory and clinical settings. Laboratory tests of backboards (200 pounds center-loaded bending) showed wide variation in stiffness ($EI = 347$ to 1766×10^3 lb – in^2). Pull-out force of skeletal pins as measured on a universal testing machine varied from 55 pounds in experimental light-weight composite tongs to over 120 pounds in Gardner-Wells tongs.

Clinical tests consist of measuring relative acceleration of the head and body and variations in traction force, integrating to yield velocities, and displacements during intra-hospital transfers, lifts, movement for therapy and diagnosis, and nursing on turning frames and kinetic beds. The procedures are done first on able-bodied subjects, then on actual patients, using 3-axis 5-g accelerometers on the forehead or the traction tongs or halo, and on the chest or back. To date, three types of cervical extrication collars, and the TACIT and Miller backboards have been tested on normal subjects using stationary IBM/PC-based digitizing hardware. Some collars require neck flexion for installation, or permit posterior translation of the head; others are prone to loss of stabilization due to posterior slipping of the chin if not fitted with greater care than is ordinarily used in practice. Time scaling of single-plane accelerations and Fourier transform analysis indicate that consistent equipment-dependent patterns are observable during such activities as log-rolling and sitting. The same measurement technique is to be applied to treatment on the turning frame and kinetic bed, and to 5-person lifting of the patient with manual traction.

Publications Resulting from This Research

Effectiveness of Cervical Spine Stabilization Devices Measured by Accelerometry. Sabelman EE, Sumchai AP, *Proceedings of the 11th Annual RESNA Conference,* Montreal, 98-99, 1988.

Measurement of Cervical Spine Mobility in a Traction Alignment, Cervical Immobilization and Transport (TACIT) Device. Sumchai AP, Sabelman EE, Eliastam M, Hargis C, *Ann Emerg Med* 17:1988.

Bending Stiffness of Backboards for Acute Spinal Injury Patient Transport. Sabelman EE, *Proceedings of the 10th Annual RESNA Conference,* San Jose, CA, 7:371-373, 1987.

Pain Secondary to Gunshot Wound During the Initial Rehabilitation Process in Spinal Cord Injury Patients

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The prevention or minimization of future pain is often cited as a reason for removal of the bullet in patients who have incurred a spinal cord injury (SCI) secondary to a gunshot wound (GSW). This study seeks to: 1) determine whether the incidence of pain reported in GSW/SCI patients is significantly different than the incidence in patients whose SCIs result from other etiologies; 2) characterize the incidence of pain reported by GSW/SCI patients epidemiologically and demographically; 3) determine the relationship between incidence of pain in GSW/SCI patients and surgical removal of the bullet; and, 4) determine, prospectively, the incidence of pain in GSW/SCI patients with or without decompression laminectomy.

Methodology—Pain data have been collected on all SCI admissions (except those excluded because of overlying psychosis or senility) on a weekly basis from time of admission to first definitive discharge, with pain behavior changes being assessed over time. Data have been evaluated with regard to epidemiologic and demographic characteristics of the population. GSW/SCI patient data are studied to determine absence or presence/location of the bullet or bullet fragment(s). If surgically removed before this phase, the presurgical location is documented. Pain history is documented and analyzed statistically.

Results—Multimodal pain ratings were recorded for 14 SCI patients with the bullet still present; 14 neurologically-matched gunshot wound SCI patients with the bullet removed; and neurologically-matched non-gunshot wound SCI controls for both groups (28 controls in all). Results suggest that persons who sustain a SCI secondary to gunshot wound report more pain than those injured in other ways. In addition, there was no indication that surgical removal of the bullet was helpful in reducing subsequent pain, either early in the rehabilitation process or at one year post-injury. Location of the bullet and type of pain which subsequently developed were not correlated with the initial decision to surgically remove the bullet.

Retrospective Analysis of the National Spinal Cord Injury Care System Database

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Purpose—Systematic, comprehensive management of acute spinal cord injury (SCI) is directed towards reducing morbidity and mortality, increasing life function capacity and minimizing costs of care associated with this catastrophic condition. Accordingly, it is desirable to establish a mechanism to evaluate performance of the organized management system addressing desired outcomes in such a way that the impact of the "system" compared to other pre-system or parallel "non-system" activities is clear. Further, assessment of "system" performance over time is essential to establish patterns of behavior which may then serve as a basis for implementing practice, policy, or programmatic change(s), if necessary. This retrospective study evaluated the performance of the Model Regional Spinal Cord Injury Care System, emphasizing quantifiable outcome variables.

Methodology—Overall system performance was evaluated using appropriate statistical procedures. The evaluation methodology included: 1) the relative proportion of all new SCIs brought into and managed by federally-sponsored Model Systems in a given year [i.e., national capture]; 2) average time between injury and system admission [i.e., mean time into system]; 3) post-admission death rate [i.e., mortality]; 4) post-admission medical complication and surgical procedure rate [i.e., morbidity]; 5) level of post-discharge independence, place of post-discharge residence, vocational outcome [i.e., life function]; 6) post-injury hospitalization experience [i.e., length of stay and readmission experience]; 7) cost characterized on the basis of appropriate epidemiologic variables to facilitate comparisons between early admission and delayed admission patients.

Results—As of May 31, 1988, the National database contained information on more than 12,000 patients. Data indicated that day one admissions have substantially shorter acute care lengths of stay. Overall lengths of stay are also substantially lowered in day one admissions. The mortality experience of system patients is markedly lower than that reported by others. Specific epidemiologic and demographic characteristics of patients admitted to the system are available in a recently-published book, *Spinal Cord Injury: The Facts and Figures*, available from the National Spinal Cord Injury Statistical Center.

Trauma Center Impact on the Disability Outcomes of Brain and Spinal Cord Injury Survivors

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Trauma centers constitute a major intervention in care for brain and spinal cord injured survivors. The purpose of this study is to document the extent to which trauma centers are changing the severity and prevalence of disability. The objectives of this study are: 1) to determine the extent to which trauma centers are increasing the survival rate of brain and spinal injured persons; 2) to determine the extent of disability among brain and spinal injured survivors; 3) to determine short-term and long-term outcomes for trauma survivors; and, 4) to determine if outcomes are mediated by selected variables such as type of injury and demographic factors.

Data from the Major Trauma Outcome Study (MTOS) will be used to determine how the probability of survival has changed over time. The MTOS database includes data on over 70,000 trauma center patients (contributed by over 85 trauma centers in the United States and Canada). Data on disability outcomes will be obtained by conducting a mail survey of survivors who have been patients at trauma centers participating in the study. The survey will obtain demographic information, information on functional outcomes in activities of daily living, and information on medical and rehabilitation utilization.

Progress—This is a 3-year project. The project is nearing the end of the first year. The following activities have been completed during the first year: 1) development of the survey instruments and data collection forms; 2) selection of cases for the pilot study and the larger study; and, 3) refinement of study protocol. A pilot study has been conducted to test study instruments and procedures. Two papers are currently being developed. One paper reviews the impact of trauma centers on survival rates. This review presents data from a number of studies which point to the favorable impact of trauma centers on survival rates. Data from the MTOS database have been analyzed and will be included in this paper. The second paper provides a review of methodological and conceptual considerations in outcome measurement of persons with brain injury.

Future Plans—Activities over the next year will involve: 1) refining the study instrument(s) and procedures based on pretest results; 2) conducting the mail survey; 3) performing preliminary data analyses; and, 4) preparing papers for publication.

Spinal Cord Injury Rehabilitation Research and Training Center on Neural Recovery and Functional Enhancement

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Department of Rehabilitation Medicine of Thomas Jefferson University has received a 5-year grant from the National Institute on Disability Rehabilitation and Research of the U.S. Department of Education to establish the first Spinal Cord Injury Rehabilitation Research and Training Center on Neural Recovery and Functional Enhancement.

The Rehabilitation Research and Training Center (RRTC) will complement the patient care programs of the federally-designated Regional Spinal Cord Injury Center of Delaware Valley (RSCICDV) Model SCI System. The RRTC program will utilize the facilities and build on the resources of the RSCICDV at the affiliated institutions of Thomas Jefferson University Hospital and Magee Rehabilitation Hospital. Under the leadership of John F. Ditunno, Jr., MD, Project Director; Gerald J. Herbison, MD, Director of Research; and William E. Staas, Jr., MD, Director of Training; spinal cord injury research and educational programs will be expanded with 14 additional research projects and 12 training programs, including the establishment of a National Resource Center on Neural Recovery.

The research will be undertaken through a highly-systematized and coordinated team approach to evaluate neural recovery and functional enhancement after traumatic spinal cord injury. The program is uniquely designed to evaluate advanced techniques and predictive measures of recovery, specific therapeutic interventions, and basic mechanisms of neural functions after spinal cord injury. Research will be conducted to determine: 1) strength, fatigue, and muscle tone in the upper and lower extremities; 2) ability to perform self-care activities and locomotion; and, 3) psychological factors which influence persons with spinal cord injury.

The research team will also study the value of specific interventions, such as: 1) cooling the spinal cord in persons with complete quadriplegia; 2) decompressing the spinal canal in older subjects with central cord injury; 3) cervical reduction after spinal dislocation; and, 4) electrical stimulation of the nerves which are not totally damaged by the spinal cord injury.

In addition, attention will be focused on defining the exact nature of neurological improvement by employing advanced electrophysiological techniques. To this end, evoked potentials will be determined by: 1) painlessly activating specific areas of the brain and recording muscle contractions in the extremities; 2) stimulating the skin of the arms and legs and recording potentials from the brain; and, 3) quantifying the extent of nerve branching in the weak muscles and nerve resupply to previously-weakened muscle fibers.

The findings of the 14 research studies will flow into the training components of the RRTC to ensure optimal dissemination of new information. Educational and training programs and learning packages on prognosis of neural and functional recovery will be provided for basic science and clinical researchers, service providers, and consumers. Training programs are planned for basic science and clinical investigators on predicting neural recovery and therapeutic interventions for functional enhancement. Specific information on prognosis will be included in other training programs for clinicians and related rehabilitation service providers such as vocational counselors and insurance rehabilitation specialists, as well as educational programs for persons with spinal cord injury and their families. The research findings will also be incorporated into ongoing Emergency Medical Service training and consumer-directed prevention.

The National Resource Center on Neural Recovery is designed to provide all concerned parties with up-to-date information on neural recovery and functional enhancement from the RRTC and from the field, and it will include a bibliographic reference service, an information hotline, and two quarterly newsletters to disseminate progress in research to professionals and to spinal cord injured consumers and their families.

Aging in Relation to Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under the auspices of the Rehabilitation Research and Training Center in Community-Oriented Services for Persons with Spinal Cord Injury, a study is being conducted of age-related effects and age-related changes in persons with spinal cord injury. The study is based upon a 2 × 2 × 2 prospective, longitudinal design that will involve 100 participants. The three independent variables are: 1) duration of injury; 2) age when injured; and, 3) measurement Occasion 1 versus Occasion 2. Three years will intervene between the two measurement occasions. Dependent variables are being assessed in six different life domains (physical well-being, psychological well-being, social integration, independence, productivity, and economic self-sufficiency); and on five moderating factors (social support, health beliefs and practices, environmental supports, perceived control, and mobility). Documented threats to physical well-being include: bacteruria, kidney or bladder calculi, renal insufficiency, pulmonary insufficiency, coronary heart disease, hypertension, spinal arthritis, heterotopic ossification, neuromuscular pain or progressive fatiguability, lipid abnormalities, and pressure sores. The psychological well-being of participants will be compared with norms for the general population in terms of life satisfaction, depression, and perceived psychological stress.

Participants are chosen on a random basis, from a cohort of more than 500 persons with spinal cord injury, who reside in a 13-county area in southeast Texas that includes the cities of Houston and Galveston. Following a home visit that includes an interview and completion of multiple self-administered instruments, participants undergo a day-long assessment at The Institute for Rehabilitation and Research that includes a physical examination, clinical laboratory assessments, X-rays, a renal scan, and provocative cardiopulmonary evaluation.

Progress—This study is in its first year, and data collection efforts are underway.

Implications—Results of this study will contribute to identifying risk factors for a number of the age-related problems of persons with spinal cord injury, and to anticipating the service needs that emerge as these persons grow older.

Life Status Study of Persons with Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under the auspices of the Rehabilitation Research and Training Center in Community-Oriented Services for Persons with Spinal Cord Injury, a study is being conducted of the life status and service needs of persons with spinal cord injury. Life status is being assessed in six domains—physical well-being, psychological well-being, social integration, independence, productivity, and economic self-sufficiency. Variance in each life domain is being explored as a function of individual difference variables particular to spinal cord injury (e.g., level and duration of injury to the spinal cord), and variables that apply to the general population (e.g., educational attainment and gender). Measures are also being obtained on five variables that are posited to moderate the relationship between the individual difference variables and the life domains. The moderating variables are social support, health beliefs and practices, environmental supports, perceived control of one's life, and mobility. Where possible, measures have been chosen for which norms are available for the general population, so that comparisons can be made.

Progress—Using a multiplicity of publicity channels and recruiting methods, a cohort has been established of persons with spinal cord injury who reside in a 13-county area in Southeast Texas that includes the cities of Houston and Galveston. A probability sample of 140 persons is being drawn from the cohort, which currently numbers more than 500 individuals. Following a home visit that includes an interview and completion of multiple self-administered instruments, participants undergo a day-long assessment at The Institute for Rehabilitation and Research that includes a physical examination, clinical laboratory assessments, X-rays, a renal scan, and provocative cardiopulmonary evaluation.

Implications—This study is based upon a representative sample from a cross-section of persons with long-term spinal cord injury, rather than a convenience sample of persons known to a particular service program. Consequently, reasonable estimates can be made of the prevalence of various problems and service needs of persons with long-term spinal cord injury. Documented threats to physical well-being include: bacteruria, kidney or bladder calculi, renal insufficiency, pulmonary insufficiency, coronary heart disease, hypertension, spinal arthritis, heterotopic ossification, neuromuscular pain or progressive fatiguability, lipid abnormalities, and pressure sores. The psychological well-being of participants will be compared with norms for the general population in terms of life satisfaction, depression, and perceived psychological stress. Other comparative data concerning social integration, functional independence, productivity, and economic self-sufficiency should contribute to the knowledge base necessary to anticipate the service needs of persons with long-term spinal cord injury.

Radiography and Radioisotopic Angiography of Spinal Cord

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Sponsor: *National Institutes of Health*

Purpose—Selective arteriography (radiographic) of the spinal cord is a diagnostic technique which has proven to be informative in cases of arteriovenous malformation (AVM), tumor, obstructive vascular disease, trauma, and postradiation damage of the spinal cord.

Radioisotope angiography of the spinal cord offers some advantages as a screening method, and in certain types of intraspinal pathology, may give information not available by other diagnostic tests.

Experience with the techniques of dynamic computed tomography, digital subtraction angiography (DSA), positron emission tomography (PET) using 18F-2-deoxyglucose, and nuclear magnetic resonance imaging (MRI) of the spine indicates that these methods may be useful screening and follow-up procedures in the evaluation of certain vascular lesions and tumors of the spinal cord.

Chemical Dependence and Spinal Cord Injury Outcome

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Sponsors: *Rehabilitation Institute of Chicago; Spinal Cord Research Foundation; National Institute on Disability and Rehabilitation Research; National Institute on Alcohol Abuse and Alcoholism*

Purpose—This report describes three currently funded projects. The common goal of these projects is to expand our knowledge about substance use by persons with spinal cord injuries (SCI). Some

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persons with SCI may be at risk for substance abuse, dependence or addiction and, as a consequence, have their rehabilitation outcome profoundly influenced by substance abuse. Early identification of persons with SCI who abuse, or are addicted to substances, or who are at risk for abuse, should decrease the cost of rehabilitation and improve rehabilitation outcome. Since the annual medical costs for all persons with SCI is estimated at $1.9 billion, timely and effective intervention for persons with cord injuries who abuse or are at risk for chemical abuse is both humane and cost-effective.

Progress—To date, we are well on our way to achieving the objectives of this study. In brief, we are seeking to: 1) describe the natural history of substance use among persons with SCI; 2) quantify the pre-injury prevalence of substance use in 20 categories; 3) validate self-report of substance use with laboratory analysis; 4) quantify the post-injury prevalence of substance use in 20 categories; 5) determine the relationship between pre-injury and post-injury substance use; 6) determine the relationships between personal, medical, social, and behavioral characteristics of persons with SCI and their patterns of substance use both pre- and post-injury; 7) determine the relationship between pre- and post-injury substance use and rehabilitation outcome, including employment; and, 8) assess the efficacy of chemical dependence interventions both before and after spinal cord injury.

This prospective project will study the relationship between substance use and rehabilitation outcome in two samples of 100 persons, one sample of persons with recent injuries, and one sample of community residents whose injuries occurred more than one year ago.

A total of 103 Rehabilitation Institute of Chicago inpatients who met the following admission criteria were recruited for the study: traumatic SCI within the last 12 months; between age 13 and 65, inclusive; no clinically significant head trauma, defined as no post-traumatic amnesia exceeding 24 hours; and, informed consent to participate (parental consent when appropriate). A total of 101 community residents have consented to participate who were recruited through the Northern Illinois Chapter of the National Spinal Cord Injury Association (NSCIA) and Access Living of Metropolitan Chicago (Access Living).

Preliminary Results—Preliminary results confirm several of our original hypotheses. Use of substances with abuse potential is prevalent before injury in this population, self-report of substance use generally is valid when compared with toxicology information, and use of some recreational, prescription, and nonprescription medications decreases after injury, while some prescription medication use increases.

Data analysis is underway to address the objectives listed above. Preparation of presentations for professional audiences and manuscripts for publication are underway.

Publications Resulting from This Research

Alcohol Use by Persons with Recent Spinal Cord Injuries. Heinemann A, Donohue R, Keen M, Schnoll S, *Arch Phys Med Rehabil* 69:619-624, 1988.

Substance Use by Persons with Recent Spinal Cord Injuries. Heinemann A, Keen M, Mamott B, Schnoll S, *Resources in Education*, ERIC Clearinghouse Number 202844.

Alcohol Use and Activity Patterns Following Spinal Cord Injury. Heinemann A, Goranson N, Ginsburg K, Schnoll S, *Rehabil Psychol* (in press).

Assessment and Prevention of Chemical Dependence Following Spinal Cord Injury

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Sponsor: *Rehabilitation Institute of Chicago*

Purpose—Chemical dependence can be related to the cause of spinal cord injury (SCI), can impair learning during rehabilitation, and can limit the vocational, social, and psychological adaptation made by individuals following SCI. There are few studies investigating substance use by persons with physical disabilities. Rehabilitation outcome may be influenced profoundly by substance abuse. Unrecognized and untreated substance dependence is likely to interfere with the intensive physical, social, vocational and psychological adjustment required following a SCI. Reliable predictors of future chemical dependence problems among persons with SCI will be essential for improving patient care and rehabilitation planning.

In brief, five major questions will be addressed by this project: 1) What is the natural history of substance use among persons who acquire SCI? 2) Can personal, medical, and behavioral characteristics of persons with SCI be used to predict substance abuse both before and after disability onset? 3) Can rehabilitation staff be trained to quickly identify substance abuse problems and make appropriate referrals? 4) What is the effect of substance use on rehabilitation outcome, including employment outcome? and, 5) What is the efficacy of chemical dependence interventions resulting from professional or self-referral?

RIC inpatients who meet the following admission criteria will be recruited for the study: 1) traumatic SCI within the last 6 months; 2) between age 13 and 65, inclusive; 3) no clinically significant head trauma, defined as no post-traumatic amnesia exceeding 24 hours; 4) informed consent to participate (parental consent when appropriate); 5) English speaking; and, 6) attending physician approves of participation.

Participants and families will be interviewed and complete instruments that assess social support, coping strategies, family adaptation, and psychological well-being. An inventory of substance use will be used to obtain data regarding all substances used prior to SCI, while a more detailed questionnaire will be administered for all substances used during the 6 months prior to SCI.

In addition, an in-service program will be developed for resident physicians, nurse therapists, psychologists, social workers, and therapeutic recreation staff members to provide them with information about the signs and symptoms of alcohol and other drug abuse and chemical dependence. A short questionnaire will be administered to them prior to training that will assess their knowledge of substance use assessment as well as the frequency with which they assess substance abuse problems and have made referrals to community resources such as alcohol and drug treatment programs, Alcoholics Anonymous, and community mental health centers in the past 6 months. Six months later, the same questionnaire will be readministered to assess any changes in knowledge and referral patterns.

An Animal Model of Incomplete Spinal Cord Injury

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Sponsor: *University of Washington, Seattle, WA; National Science Foundation*

Purpose—Recovery of voluntary movement is characteristic of incomplete spinal cord injury (SCI). Such recovery is observed even though a majority of descending axons are sectioned and degenerative. They do not regenerate; rather, the spared descending axons apparently assume or substitute for some of the lost functions. This research undertakes to develop an animal model for investigating the mechanisms that mediate recovery and any interventions which might enhance recovery.

Progress—Adult rats undergo mid-thoracic subtotal spinal cord section, sparing either one ventral or one lateral funiculus. Hindleg locomotor and postural recovery and spinal reflex changes are described over 4 to 6 weeks after the cord lesion. Some locomotor recovery is supported by fewer than 25 percent of descending fibers, and neither the dorsal half of the lateral funiculus nor the medial half of the ventral funiculus is necessary to mediate that recovery. Anterograde labeling of lumbar commissural axons and terminals, crossing from the side of the cord with spared descending fibers to the side without spared fibers, has failed to demonstrate any morphologic changes in this projection to explain the motor recovery. However, quantitative studies suggest an increased bouton density per length of axon in the medial ventral horn, indicating sprouting of new terminals.

Some rats were placed in immobilization tubes for 3 to 4 weeks after a subtotal spinal cord lesion. Immobilized rats showed no significant locomotor recovery during the period of immobilization, in contrast to freely mobile animals with similar cord lesions. Immobilized rats without cord lesions showed minimal deficits. Thus, hindlimb activity is necessary for this locomotor recovery.

Future Plans—These studies suggest that synaptogenesis by spared commissural pathways in the lumbar cord may contribute to locomotor recovery, and that neural activity is essential for that recovery to develop. This animal model of incomplete spinal cord injury will be used in trials of therapeutic interventions which may enhance recovery.

B. Medical Treatment

Enhanced Healing of Skin Ulcers

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A447-RA)*

Purpose—The purpose of this project is to accelerate wound area reduction in patients with chronic skin ulcers using artificial skin, electrical stimulation, and hyperbaric oxygen treatment. Preliminary results indicate that wound area reduction can be achieved using a Type I collagen matrix.

Progress—Type I collagen in a porous sponge form attracts fibroblasts in culture and accelerates the repair of animal wounds. Type I collagen sponge and flakes were packed into stage II and III skin ulcers on patients 35 to 70 years of age. Patients included in the study exhibited loss of dermal tissue without exposure of muscle, tendon or bone, and did not show signs of venous stasis or diabetes.

All patients had their wounds traced on clear plastic sheets for 3 weeks prior to initiation of the collagen treatment. During this period ulcers were cleaned and debrided daily. Collagen treatment was initiated on the fourth week provided that the wounds were free of pus and dead tissue. Three out of 7 patients treated with a collagen sponge , and 12 out of 14 patients treated with collagen flakes showed a 40 percent decrease in wound area after 6 weeks of treatment. In comparison, 18 control patients showed no change in wound area over the same time interval. These results indicate that collagen flakes are effective in initiating healing of skin ulcers.

Studies are now in progress to evaluate the effect of the addition of fibronectin and/or hyaluronic acid (to the collagen flakes) on healing of skin ulcers. These macromolecules are known to attract fibroblasts into a collagen sponge in an animal model.

Future Plans—Cell culture and animal studies are underway to evaluate the seeding and growth conditions for large cultures of fibroblasts and epidermal cells on Type I collagen matrices. Preliminary results suggest that fibroblasts can be grown on porous sheets and beads of Type I collagen in culture on a large scale, and that fibroblast-seeded collagen matrices increase the strength of animal dermal wounds when compared to collagen matrices that are not seeded.

Future studies will include large scale culture of human fibroblasts and epidermal cells on collagen beads in a biochemical reactor. These beads will be used to accelerate the rate of dermal and epidermal repair of human skin ulcers. Results of tissue culture studies indicate that epidermal cells divide and form several layers of keratin-producing squamous cells when grown in culture on a collagen matrix. In some cases a basement membrane is observed by transmission electron microscopy beneath basal cell layers. In contrast, when epidermal cells are grown in the pores of a collagen sponge they form gland-like structures.

Can Spinal Cord Injury be Reduced by Blocking Calcium Channels?

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Sponsor: *American Paralysis Association*

Purpose—Injury to cells causes an increase in the intracellular concentration of calcium. This influx is known to activate a number of events that eventually leads to cell death. Drs. Gardner and Bridges will explore the hypothesis that if the entry of calcium can be prevented, the spinal cord could be saved from the disastrous consequences of spinal cord injury (SCI). This hypothesis is supported by recent work in brain tissue in which calcium blocking reduced neural degeneration by 70 percent. Two channels for calcium entry into cells will be explored: the NMDA receptor system and the voltage-gated calcium channel. Specific agonists and antagonists of these channels will be studied to define specific biochemical mechanisms associated with calcium-mediated neuronal degeneration in the spinal cord.

Mechanisms of Steroid Hormone Therapy in the Paralyzed Nervous System

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Sponsor: *American Paralysis Association*

Purpose—We are proposing a series of studies to explore the utility of testosterone as an aid in treatment, following nervous system injury. The model system that will be used is the adult hamster facial motor nerve cell. In the first experiment, we will determine if testosterone can accelerate recovery from facial paralysis. Then, the capability of testosterone to rescue immature hamster facial motor nerve cells, which would otherwise die following injury to their nerve fibers, will be explored. In the final set of experiments, it will be determined if testosterone acts on nerve cells through a heat-shock-like mechanism.

Implications—The results will provide 3 new directions for future clinical and experimental studies concerning the curative potential of steroid hormone therapy in nervous system injury and paralysis.

Control and Repair of Central Nervous System Injury

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Sponsor: *American Paralysis Association*

Purpose—In this laboratory, three issues involved in an integrated approach to central nervous system (CNS) injuries are being explored: 1) prevention of secondary neuronal death; 2) stimulation of neuronal activity in chronic spinal injuries; and, 3) control of gliosis.

Future Plans—In the present year of this research activity, based on this laboratory's previous results, treatment with compound MK-801, to prevent secondary neuronal death following spinal contusion, will be optimized. Also, chronically-injured animals will be treated with the potassium channel blocker, THA, which is expected to help recovery by increasing neuronal excitability and thereby activating "silent" circuits. These researchers will continue work on their newly-discovered epidural growth factor (EGF) receptor-related gliosis inhibitor. These are naturally-occurring molecules, the purification of which appears feasible, and which should allow the control of astrocyte response.

Drug Effects on Bladder Smooth Muscle Contractility

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Debilitating spasticity is an extremely serious secondary complication in patients with spinal cord dysfunction. Skeletal muscle relaxants are commonly prescribed to counteract spasticity, but experience has shown widely varying degrees of success. The bulk of previous research has addressed their effects on skeletal, and to a lesser extent, cardiac muscle. Their effects on smooth muscle have been considered only rarely. This study examines the role of skeletal muscle relaxants on arterial and intestinal smooth muscle contractions in rats and on bladder smooth muscle in humans. Objectives of this study include: 1) determination of the effect of baclofen (Lioresal) and diazepam (Valium) on *in vitro* human bladder smooth muscle contractions induced by electrical pulses or acetylcholine; 2) determination of the effect of baclofen and diazepam on *in vitro* rat and dog arterial and intestinal smooth muscle contractions induced by electrical pulses or acetylcholine; 3) determination as to whether diazepam or baclofen alter the responses of rat and dog bladder, arterial and intestinal smooth muscle induced to contract by bethanechol chloride; and, 4) determination as to whether diazepam or baclofen alter the length-tension relationship of rat and dog bladder, arterial and intestinal smooth muscle.

Methodology—Smooth muscle tissue specimens will be obtained surgically in accordance with institutionally approved guidelines governing the involvement of human subjects in research projects. *In vitro* tension measurements resulting from artificially induced contractions under control and experimental (with drug) conditions will be obtained. Interspecies drug effects on different tissue specimens will be determined and compared.

Preliminary Results—Smooth muscle tissues from small intestine, blood vessels, and urinary bladder were obtained from 75 rats and 10 dogs. All experiments began with the establishment of a dose-response relationship between acetylcholine or bethanechol concentration and resting and active tension. Shifts in the dose-response curves were assessed to shed light on mechanisms of action of the drugs under study. Our overall conclusion to date is that drugs that block calcium ion influx may diminish urinary bladder tone. The clinical relevance of this observation is that drugs used to reduce skeletal muscle spasticity may spare the bladder smooth muscle and allow normal or near normal bladder muscle tone to be maintained.

Future Plans—Differential effects of the drugs of interest will be tested in smooth muscle of different types and in different experimental animals. We will reinforce our efforts to obtain human smooth muscle samples for the study to facilitate our understanding of the clinical relevance.

Effect of Intermittent Catheterization in Renal Stone Formation in Spinal Cord Injury Patients

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Because spinal cord injury patients commonly experience alterations in calcium metabolism (hypercalciuria) which may persist for many months after injury, it is necessary to determine how, if at all, intermittent catheterization in the presence of hypercalciuria affects the risk of urinary tract stone formation. This study seeks to examine the effects of intermittent catheterization and determine the significance of hypercalciuria in spinal cord injury (SCI) patients.

Methodology—The study population consists of patients with neurologically complete spinal cord injuries who are identified and entered into the study within one week of injury. Twenty-four hour urine specimens are collected at admission and twice weekly thereafter until the patient is discharged. Serum calcium is measured. Urine pH and species concentration measurements are obtained at regular intervals. Relative supersaturation of the urine with respect to calcium oxalate and calcium phosphate is determined. Activity product and the formation product ratio of brushite is determined for each specimen.

Results—It was somewhat more difficult to identify and enroll prospective study subjects than originally anticipated. Fifteen patients with neurologically complete spinal cord injuries were started on the protocol within 1 week of injury; 9 patients were followed for 5 weeks. Of these 9 patients, only 5 were started on intermittent catheterization protocol (ICP). The average length of follow-up after initiating ICP were 4 weeks. None of the patients were hypercalcemic. Six patients had hypercalciuria on at least one occasion. Among those patients, urinary calcium excretions returned to normal within 8 weeks of injury. No consistent changes were found in the excretion pattern of other urinary constituents. In conclusion, we believe it is worthwhile to measure urinary calcium excretion prior to starting ICP. If the urinary calcium excretion is markedly elevated, ICP could be postponed for several weeks. Since all of our patients were normocalciuric within 8 weeks of injury, such postponements would be of reasonably short duration.

Pathologic Effects of Recurrent Bacteriuria in Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Urinary tract infections (UTIs) are a serious source of morbidity for spinal cord injury (SCI) patients. Recurrent hospitalizations and outpatient services required for treatment of acute and chronic UTIs are extremely expensive and may impede both the rehabilitation process and vocational pursuits. In addition, UTIs may lead to grave urologic complications and, in some cases, eventual renal failure. There is a need to prevent these infections and their sequelae so as to improve the overall rehabilitation potential and quality of life for SCI patients. Objectives of this study include: 1) determination of the incidence of clinically significant urinary tract complications coincident with the major bacterial species; 2) determination as to whether aggressive treatment of most pathogenic organisms results in fewer long-term secondary urinary tract complications; 3) determine if patients with certain human leukocyte antigen (HLA) combinations are at unusually high or low risk for developing long-term secondary urinary tract complications; 4) determine if the phagocytic activity of human leukocytes correlates with the incidence of clinically significant UTIs and long-term secondary complications; and, 5) determine if the degree of bacterial adherence to the urothelium correlates with the incidence of clinically significant UTIs and specific HLA combinations.

Methodology—Data will be analyzed to determine the effect of chronic UTI with the major bacterial species on parameters such as parenchymal thickness, reflux, effective renal plasma flow, etc., by selecting SCI patients who have been infected for 1 year or more and comparing their data with those of uninfected patients. SCI patients with histories of multiple urinary tract complications will be studied to determine if: 1) their bacteria show a high degree of adherence to the urothelium; 2) there is a particular HLA combination; or 3) they have circulating leukocytes or monocytes of unusually low phagocytic activity when compared with SCI patients who rarely or never have UTIs, and with persons without SCI who have normal urinary tracts. SCI patients with recurrent UTIs will be treated rigorously with antibiotics and followed. The effectiveness of rigorous follow-up and treatment will be assessed via comprehensive renal scintigraphy procedures, excretory urograms and carefully documented reinfection rates.

Preliminary Results—The first two years of this project have been devoted to perfecting laboratory techniques. We have experimented with several different assays for measurement of phagocytosis and bacterial adherence, and settled on suitable, reproducible and accurate methods to accomplish the stated objectives of the clinical phase of this project. Representative samples of catheterized urine from SCI patients have been evaluated for enumeration of adherent bacteria. We are currently evaluating methods for freezing and preserving uroepithelial cells from these patients so that additional adherence assays using their own or standard bacterial isolates can be performed.

Future Plans—Patients will continue to be enrolled into the study. An additional objective will be addressed: we will attempt to determine the prevalence and significance of genital mycoplasmas in this population.

Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires: 1) knowledge of the natural history or clinical course of urinary tract complications in this group; and, 2) data from which to determine whether urinary complications in this group are predictable from early post-injury urinary tract status and method of early bladder drainage management. The objectives of this study include: 1) determining the effect of method of bladder drainage management on the incidence of orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyelocaliectasis, and effective renal plasma flow (ERPF); 2) determining the effect of various urinary tract infecting organisms on orchitis/epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyleocaliectasis, and ERPF; and, 3) determining the effect of vesicoureteral reflux on upper tract changes including ureterectasis, pyelocaliectasis, calculi, and ERPF.

Methodology—Rigorous statistical analyses are being performed on a massive urologic database derived from a large series of SCI patients having a spectrum of neurologic levels and extents of injuries.

and whose neurogenic bladders are/were managed in a variety of ways.

Preliminary Results—Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 777 patients from a prospective group, yielding a total of 1,104 completed studies to date. A case-control study (n = 126) was conducted to identify and quantify risk factors for vesicoureteral reflux. All risk factors were assessed at the time of diagnosis for patients with vesicoureteral reflux and at a comparable time post-injury for controls. Bladder management method was the most potent risk factor ($p < 0.0001$). Cases were also more likely to have neurologically complete lesions and have had an episode of chills and fever in the preceding year.

Future Plans—Data collection is continuing. In addition to the above objectives, we plan to develop a transportable urologic complication database and data collection protocol which should enable external clinical investigators to participate in collaborative post-SCI urologic complication research efforts.

Didronel in the Prevention of Heterotopic Ossification Following Spinal Cord Injury: Determination of an Optimal Treatment Schedule

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Heterotopic ossification (HO) following spinal cord injury (SCI) or other severe neurologic injuries and diseases can limit joint range of motion and exacerbate the disability, often impairing function and limiting ambulation or wheelchair independence to the extent that the patient must remain bedfast. Recently, however, a new drug, didronel (etidronate disodium), has been shown effective in preventing HO when administered prophylactically after SCI. This study seeks to: 1) determine the optimal time post-injury didronel therapy should be initiated to achieve the maximal prophylactic effect; 2) determine the optimal duration of didronel therapy for maximal prophylactic effect; and, 3) establish dosage recommendations for didronel that are capable of yielding maximal prophylactic effect.

Methodology—The study population consists of patients admitted to the UAB-Spinal Cord Injury Care System between 0 and 120 days post-injury, whose lesions are neurologically complete (or neurologically incomplete with residual function equal to a Frankel Classification of "sensory only"), who are at least 16 years of age and who are not pregnant. Patients in the series are subcategorized into Early and Late Treatment Groups and further divided into 3- and 6-month administration groups. X-ray films of both hips are obtained one day prior to initiation of didronel therapy, at the end of each treatment period and at one year post-injury.

Results—This study was completed on May 31, 1988, with a total of 118 patients whose compliance was acceptable. The overall results show that during treatment and after treatment, 27.1 percent of the early treatment group developed some degree of HO, compared to 43.8 percent in the late treatment group. Similarly, during treatment, 16.9 percent developed some HO in the early treatment group, whereas 33.9 percent developed some HO in the late treatment group. This suggests that early treatment is preferable to later treatment, and correlates well with the clinical impression that most HO develops within one to four months after injury.

Value of Electrical Stimulation on Fertility in Male Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Infertility is a major problem among male spinal cord injury (SCI) patients. In fact, infertility rates range from 99 percent for neurologically complete quadriplegics to 90 percent for neurologically incomplete paraplegics. This study seeks to: 1) determine optimal conditions for producing seminal emission via electrical stimulation of the pelvic sympathetic nerves; 2) compare electrical stimulation with strong vibratory stimulation of the genitalia in eliciting seminal emission in male SCI patients; 3) determine if repeated stimulation improves semen quality (sperm count, motility, and morphology); 4) determine if intermittent testicular cooling improves semen quality; 5) relate success or failure of seminal emission production to neurolevel and extent of spinal lesion, urodynamic assessment of lower urinary tract function and incidence of recurrent urinary tract infection; and, 6) artificially inseminate a male SCI patient's female partner who had been unable to be impregnated since the patient's injury.

Methodology—Male SCI patients voluntarily participating in the study are randomly assigned to electrical stimulation or vibratory stimulation groups. Seminal emissions are acquired and the sperm examined for viability. Patients failing to produce viable sperm in either group undergo stimulation with testicular cooling. Viability of sperm produced is determined. Success/failure of seminal emission production is assessed statistically. Female partners of patients with satisfactory sperm production by either modality will be evaluated physically and, if in good health, artificially inseminated.

Preliminary Results—Eighteen patients have been entered in the study. A total of 13 have undergone electrical stimulation. All patients produced an ejaculate. Most had adequate sperm counts; however, motility has been less than 15 percent for all but two patients.

Future Plans—Patients will no longer be randomly assigned to the vibratory or electrical stimulation groups. All patients will be given a two- to three-month trial in the vibratory stimulation group prior to switching to the electrical stimulation group. Patients who are unsuccessful with both types of stimulation will be offered the opportunity to participate in a study of direct aspiration of sperm from the surgically-exposed proximal vas deferens.

Incidence, Characteristics and Clinical Significance of Anemia in Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Anemia commonly develops within the first six months following spinal cord injury (SCI), even in the absence of detectable blood loss. Whether anemia is due to stress, inadequate nutrition, blood loss, depressed red blood cell (RBC) production or increased RBC destruction has not been determined. Anemia may be an important factor in the development of secondary complications. It may also delay or prolong the rehabilitation program. Thus, finding the cause of anemia in this population is a requisite to its prevention. This study seeks to: 1) determine those epidemiologic and/or demographic variables affecting the duration and/or severity of anemia; 2) determine the natural history of changes in the hematologic profile of SCI patients; 3) establish the natural history of RBC kinetics after SCI; and, 4) determine whether alterations in nutritional profile are associated with the incidence, duration and/or severity of post-injury anemia.

Methodology—A series of neurologically complete quadriplegics (who did not receive blood transfusions following their SCI) constituted the study population. Demographic characteristics and the hematologic correlates of the population were documented as were basic hematologic profiles. Ferrokinetic studies were performed. Nutritional profiles and their hematologic correlates were established. Erythropoietin quantitative assays were performed. All data were analyzed utilizing appropriate statistical techniques.

Results—The study population was comprised of 26 male and two female quadriplegics (C3 to C7). No persons had below-normal blood volumes or plasma volumes. However, 73 percent had below-normal red cell masses, 25 percent had below-normal serum erythropoietin levels and 11 percent had below-normal reticulocyte counts. Most persons (71 percent) were found to have normochromic, normocytic anemia, while four persons (14 percent) had normochromic microcytic anemia. Only four persons (14 percent) did not develop clinically significant anemia. Although these cases of anemia were not severe enough to require transfusions, they might be an important factor in the development of other secondary complications and may combine with other nutritional and hematologic deficiencies to prolong the rehabilitation process.

Effects of Nutritional Intervention During the Acute Phase of Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this project was to determine the potential benefits of providing persons with spinal cord injury (SCI) with supplementary ascorbic acid during the rehabilitation phase of treatment. Since persons with SCI demonstrate both depressed immune responses and decreased plasma ascorbate levels, it is important to determine whether supplementary ascorbic acid therapy can improve the immune responses and decreases the incidence of secondary complications commonly seen during the first few months post-injury.

Methodology—This study was a randomized, placebo-controlled, double-blind investigation. Patients were assigned to either usual care or supplemental ascorbic acid support (300 mg daily).

Results—Twelve patients were enrolled in the study. Respiratory function appeared to be slightly enhanced in the treatment group, although this difference was not a statistically significant one. There was no apparent effect of treatment on immune function. Due to problems in patient recruitment and the minimal effects of supplementary ascorbic acid support in preliminary findings, this project was discontinued.

Deep Vein Thrombosis: Prophylaxis in Acute Spinal Cord Injured Patients

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Sponsors: *National Institute for Disability Research and Rehabilitation; The 3M Company; Sandoz Research Institute*

Purpose—The purpose of this prospective, randomized study was to evaluate the efficacy of low-dose heparin, alone or in combination with electric stimulation, in the prevention of deep vein thrombosis (DVT) in C_2 to T_{11} motor complete and incomplete-preserved motor, nonfunctional spinal cord injured patients.

Methodology—The tibialis anterior and gastrocnemius-soleus muscle groups were stimulated bilaterally, using 50μ pulses given at 10Hz with 4-second "on" and an 8-second "off" cycle for 23 hours daily over a 28-day period. Forty-eight patients, less than 2 weeks after injury, were randomly assigned to saline placebo ($n = 17$), low-dose heparin (5,000U, subcutaneous every 8 hours) ($n = 16$), and low-dose heparin plus electric stimulation ($n = 15$). A normal 125-I fibrinogen scan and impedance plethysmography were required for entry into the study. Surveillance for DVT was evaluated by daily 125-I fibrinogen scanning. Venography was performed to confirm a positive impedance plethysmography and/or 125-I fibrinogen scanning tests for 2 consecutive days and at the completion of the study.

Results—The incidence of DVT was 8 of 17 in the placebo group, 8 of 16 in the low-dose heparin group, and 1 of 15 in the electric stimulation plus low-dose heparin group. The use of electric stimulation plus low-dose heparin significantly ($p<0.05$) decreased the incidence of DVT compared to the other treatments.

Sacral Surface Stimulation for Bladder Management of Patients with Spinal Cord Injury

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Sponsor: *Neuroscience and Aging Institute, Loyola University, Stritch School of Medicine*

Purpose—Control of bladder functions of continence and voiding are lost in many spinal cord injured (SCI) patients. Because of this lack of control, several problems can occur, including urinary incontinence, urinary infection, and high bladder pressures which can result in urological pathology. There is a need, therefore, for control of these bladder functions.

Sacral stimulation has been effective in clinical trials for managing bladder functions, using cuff electrodes on sacral ventral nerve roots within the sacral canals. However, invasive surgical implantation procedures including laminectomy and entry inside the dura for implanting nerve cuff electrodes have been required. We have been evaluating less-invasive methods of sacral nerve stimulation in the chronic spinal male dog. These methods include sacral surface electrodes and implanting electrodes in the sacral canal, using percutaneous procedures. Based on encouraging results, we are initiating trials in SCI patients with surface electrodes over sacral foramina.

Progress—Three male patients with thoracic spinal injuries have been evaluated. Four tests are being conducted to evaluate bladder management with sacral surface stimulation. 1) Determine optimum electrode arrangements: surface electrodes over the

S2 sacral foramina appear to be optimal. 2) Determine optimum parameters for bladder voiding and bladder inhibition: preliminary observations indicate that stimulating currents over 70 mA will be needed for effective treatments. As our current stimulator is inadequate, we are currently contracting for a high current surface stimulator. 3) Evaluate the safety of sacral surface stimulating procedures: procedures have been safe as little or no changes in heart rate or blood pressure have been noted. 4) Determine urodynamic responses: effective voiding on bladder inhibition remains to be shown.

GABA Agonist/Antagonist Effects on Locomotor Recovery Following Subtotal Spinal Cord Lesions

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Traumatic spinal cord injury in humans is often followed by some recovery of voluntary movement below the injury. In some individuals, the recovery allows return of motor function; in others, the recovery is minimal and movements are nonfunctional. Recent observations suggest that the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) may enhance motor recovery within the spinal cord. This study examines the effect of a GABA agonist and a GABA antagonist on motor recovery in an animal model of spinal cord injury.

Progress—Adult rats have undergone mid-thoracic 3-quarter lesions of the spinal cord, sparing the left ventral funiculus. These rats are assigned to 1 of 3 groups. Group 1 received Baclofen, a GABA agonist, through a daily intraperitoneal injection for 4 weeks. Group 2 received Bicuculline, a GABA antagonist, through daily intraperitoneal injection for 4 weeks. Group 3 is composed of control animals. The temporal course and final level of motor recovery are observed over an 8-week period. To date, we have not observed any significant differences in the rat or in the final level of motor recovery which can be attributed to the baclofen or bicuculline treatments.

Future Plans—Future studies will investigate the intrathecal administration of baclofen and bicuculline to obtain a greater local effect on the spinal cord with fewer systemic side-effects. Such studies will guide future clinical investigations on the early use of spasmolytics in patients with incomplete spinal cord injury.

C. Spinal Cord Regeneration

Hormonal Control of Neuronal Growth in Adult Spinal Cord

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Sponsor: *American Paralysis Association*

Purpose—The researchers in this laboratory have recently discovered that testosterone induces a dramatic growth of dendrites in a specific group of motoneurons in the rat lumbar spinal cord. Castration was found to reduce the length of rat dendrites by over 50 percent, and androgen treatment of castrated animals caused complete regrowth of dendrites. The associated changes of synaptic input to these motoneurons suggest that the neuronal circuit is disconnected with castration and reconnected with androgen treatment. With greater understanding of the factors that facilitate or limit this hormonally induced growth, the unexpected plasticity in the adult rat model shows promise for use in treatment of patients with spinal cord injury. In the proposed project, Dr. Arnold will conduct two studies: 1) to measure precisely the growth induced by hormones; and, 2) to determine which types of motoneurons are affected by hormones in the fashion described above.

Neural Tissue Transplantation for Spinal Cord Injury

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Sponsor: *American Paralysis Association*

Purpose—This project is a study of the transplantation of brain tissue as a means of promoting regeneration of spinal cord after injury in laboratory rats. A rat model with contusion injury of the spinal cord has been standardized in this laboratory. This model of cord injury will be used, since it corresponds to the usual mode of cord injury in humans. Immediately after injury in adolescent rats, brain tissue from fetal rats will be transplanted by injection into the spinal cord of the injured rats at the site of injury. The strength and sensation in the hind legs will be tested over the course of 3 months following injury and brain tissue transplant, to determine the degree of functional recovery. The animals will then be sacrificed, and the spinal cords will be examined microscopically to identify the effect of transplanted tissue on the spinal cord. The extent of functional recovery of the hind limbs will be correlated with cellular changes in the injured spinal cords.

Morphological Properties of Regenerated Motor and Sensory Neurons

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Sponsor: *American Paralysis Association*

Purpose—The immediate response of mammalian peripheral neurons to axonal injury has been extensively examined, with the intention of identifying factors that facilitate regeneration in this system and to investigate their usefulness in modifying recovery in the central nervous system. Less attention has been focused on more delayed alterations in regenerated neurons, although several lines of evidence indicate that abnormalities persist beyond one year following injury. Recently, striking structural changes have been identified in spinal motor neurons examined one year after crush injury to the sciatic nerve. Such changes have not previously been described and may represent late-occurring sequelae of nerve injury. The experiments in this project will further characterize these morphological changes for both motor and sensory neurons, in order to answer two general questions: 1) Do morphological changes progressively develop following axonal injury or are they a late occurrence following full recovery? and, 2) Do such structural changes develop following nerve injury in all cell types or are they limited to motor neurons? Morphological examinations of both motor and sensory cells giving rise to regenerated axons will be performed at 5 and 10 months following nerve lesions. Data will be analyzed to permit comparison of changes between motor and sensory cells at both post-lesion examinations.

Contribution of Spinal Cord Transplants to Recovery of Function and Anatomical Repair after Injury to the Developing Spinal Cord

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Sponsor: *American Paralysis Association*

Purpose—Dr. Bregman and her colleagues are interested in the effects of spinal cord transplants on recovery of function and in exploring some of the determinants of these effects—particularly those associated with developmental processes. Specifically, in this research, the contribution of four representative neural pathways (i.e., corticospinal, raphe-spinal[serotonergic],coeruleo-spinal[noradrenergic] and dorsal root afferents) to recovery will be studied in rats that receive spinal cord lesions and transplants at birth. Second, an attempt will be made to define the conditions that change over the course of development resulting in the more limited anatomical plasticity of the adult. Dr. Bregman's work is based on the hope of parlaying triggers for neural growth that may be found in newborns to become triggers in the neural system of the adult.

Response of Developing Astroglia to Injury

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Sponsor: *American Paralysis Association*

Purpose—In their prior work, these researchers have shown that the view of the astrocyte as simply a scar cell, which at best is space-filling, and at worst an impediment to effective nerve cell regeneration and reconnection, is too simple. "Thus, some astrocytes provide the paths for cell migration, others the cues for their position, and still others form scar tissue in the central nervous system (CNS)." In this project, Drs. Hatten and Mason will determine what the biochemical and cell biological properties of astrocytes from sites of injury in the CNS are, how they differ from growth-supporting astrocytes in the developing brain, and in doing so, determine what roles these cells might play in hindering or facilitating functional repair in the CNS. Specifically, they will attempt to purify astrocytes from areas of brain injury, and bring them into culture where their interactions with normal, uninjured neurons can be contrasted with the interactions of astrocytes that have not been injured.

Can Human Schwann Cells be Propagated for Transplantation?

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Sponsor: *American Paralysis Association*

Purpose—Recent animal studies have shown that implanted Schwann cells act to enhance regeneration in the spinal cord, either by direct interaction with axons, or indirectly via the production of neuronotrophic factors as a favorable extracellular environment for regeneration. The potential role of Schwann cells in aiding regeneration is hampered by a lack of basic information about mitogenic characteristics and their functioning after multiplication. In this research, the proliferation rate of Schwann cells is being studied under three conditions: 1) cells maintained in a serum-enriched medium; 2) cells in the presence of a growth factor with known mitogenic potential; and, 3) cells in the presence of neurites. The functional capabilities, ensheathment, and myelination of the cells in each of these contexts will be determined by placing Schwann cells in contact with human dorsal root ganglion neurons.

Thy-1 and Process Regeneration by Central Mammalian Neurons

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Sponsor: *American Paralysis Association*

Purpose—We will extend prior work, performed on retinal nerves, to spinal cord neurons. In previous research we explored the role of "Thy-1 antibodies" in aiding regeneration. Thy-1 is a component of the surface of nerve cells. In this project, we will attempt to isolate a Thy-1 receptor. Working on the assumption that the Thy-1 receptor will also promote regeneration, and, since it is a naturally occurring substance, it may prove more useful than antibodies.

Implications—If we are successful in isolating and purifying the receptor for Thy-1, the study of the structure of this receptor will tell us about molecules that make parts of the nerve cell re-grow. Thus, this research will have far-reaching implications for regeneration following injuries, due to stroke or spinal cord injury.

Facilitation of Spinal Cord Regeneration by Nerve Growth Factor

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Sponsor: *American Paralysis Association*

Progress—The functional properties of spinal cord and brain cells depend on a constant supply of molecular signals provided to them by their surroundings. When a neuron and/or its axon process is damaged, the cell can become cut off from, or unable to respond to, a number of these signals, some of which may be required for the neuron to retain function. One signal, nerve growth factor (NGF), is required for the survival of certain peripheral nervous system neurons and their axons, both in tissue culture and in the intact animal. Recent evidence from several laboratories, including this one, has shown that NGF can prevent trauma-induced degeneration of certain adult rat brain neurons. In the first year of this project, results indicate that purified NGF, administered at the time of spinal cord damage, can prevent the resulting degeneration of cerebral cortex neurons that send long axons down the spinal cord. In the current year, this laboratory is repeating this experiment with a larger number of animals, to determine if the NGF therapy is equally effective when started long after the spinal cord is damaged, and also to determine if the factor can promote regeneration of the transected corticospinal axons across the site of spinal cord damage.

Rebuilding of a Functional Motoneuronal Innervation of Deafferented Muscles after Excitotoxic Lesion of the Ventral Spinal Cord

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Sponsor: *American Paralysis Association*

Purpose—Three studies are being undertaken in this research: 1) The ability of spinal cord embryonic neurons to grow and differentiate in the excitotoxically-lesioned spinal cord will be evaluated, using light microscopy, associating histochemical, and immunocytochemical labeling to identify motoneurons; 2) Means to obtain the growth of axons of transplanted neurons in the emptied ventral root, using peripheral nerve guides, will be defined. Evaluation of the growth will be based on axonal tract tracing techniques; and, 3) The effect of neuromuscular reconnections on atrophy and muscular function will be evaluated. Reduction of atrophy, muscular constriction during electrical stimulation of the corresponding ventral root, as well as morphological and electrophysiological characteristics of the neuromuscular junctions, will be used to determine the functional status of possible neuromuscular reconnections.

Control Mechanisms of Central Nervous System (CNS) Regeneration

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Sponsor: *American Paralysis Association*

Purpose—The main goal of this research is to study the molecular mechanisms that control nerve fiber growth and regeneration. In particular, Dr. Pfenninger and his research team are: 1) searching for hormone-like factors that stimulate the growing tips of nerve fibers, the nerve growth cones; and, 2) studying the biochemical responses of the growth cones to the growth factors. Their focus in this 3-year study is on a peptide factor, which they will purify and characterize its chemical and functional properties. They will also analyze the biochemical processes activated by the interaction of the peptide factor with the growth cone membrane. These researchers are working on the premise that growth regulatory mechanisms may become the targets for drugs to promote nerve growth; and growth factors, once identified, may be used directly to promote regeneration in the CNS.

Enhancement of Spinal Cord Regeneration by Trophic Substances

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Sponsor: *American Paralysis Association*

Purpose—In this research, the impact of applying potentially trophic substances (i.e., Schwann cells, axolemmal fragments, and gangliosides) on regeneration of nerve cells across a complete transection of the spinal cord, will be studied, using a rat model. A scaffold coated with laminin will serve as a bridge for axonal regeneration across the spinal transection; if the scaffold technique does not work, peripheral nerve bridges will be inserted across the transected cord instead. The effects of the trophic treatments on regeneration will be assessed by the injection of horseradish peroxidase into the spinal cord, on one side of the injury, to determine if this tracer substance can be detected on the other side, as evidence of transport through regenerated fibers. Electrophysiological techniques will also be used to monitor regeneration.

Functional and Molecular Differences of Immature and Mature Astrocytes

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Sponsor: *American Paralysis Association*

Purpose—Functional recovery from a central nervous system (CNS) lesion decreases dramatically with maturation in mammals. The cellular basis of this change is unclear, but thought to be related to the formation of glial scarring. Recently, this laboratory has shown that millipore filters coated pre dominantly with neonatal astrocytes, greatly reduce scar formation when transplanted into adult brains; and that these neonatal cells act as a suitable substrate for axonal outgrowth in adult animals. Uncoated implants, or those coated with astrocytes from mature animals, did not have these effects. In the present research, both cellular and molecular differences between mature and immature astrocytes are being examined, with a focus on their capacity to support axon outgrowth *in vitro*. These two populations of astrocytes will be examined for biochemical differences, and both polyclonal and monoclonal antibodies will be generated against membrane proteins specific to immature astrocytes. These immunological reagents will be used to understand the molecular basis for neurite outgrowth and inhibition of glial scarring by immature astrocytes, and perhaps to modulate their expression in the adult animal.

Transplants of Fetal and Adult Adrenergic Cells in the Adult Spinal Cord

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Sponsor: *American Paralysis Association*

Purpose—This laboratory's research has focused on determining if fetal or adrenal medullary cell implants restore specific functions in chronically and acutely lesioned spinal cords. Their previous work demonstrated that transplants of either fetal neurons or adrenal cells reversed alterations of spinal cord function which were induced by destruction of specific spinal cord motor pathways, demonstrating an effect in acutely injured animals. They will now determine the effects of implanting either adrenal cell "clones" (adrenal cells that are grown using cell culture techniques) or fetal neurons into chronically damaged spinal cords. The impact of implants on functioning will be looked at behaviorally and also in terms of EMG patterns associated with specific behavioral patterns. Also, the extent of outgrowth of implanted cells will be analyzed using histofluorescence methods. Two other objectives will be addressed: 1) testing the effects of growth factors in augmenting the effects of the implants; and, 2) studies to clarify optimal conditions for culturing the cells that are used in this research.

Regeneration of Adult Central Nervous System (CNS) Myelin: In Vitro Analysis

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Sponsor: *American Paralysis Association*

Purpose—This laboratory has been exploring myelin regeneration, using a tissue culture model. Glial cells from immature or adult mouse optic nerves migrate into a fragment of cerebellum from another mouse, and make myelin around the cerebellar axons.

Progress—During the initial phase of this project, it was found that: 1) myelin is successfully formed by glia from mice as old as one year; 2) computerized 3-D reconstruction of the experiments provides much more information about migration distances and trajectories than can be obtained otherwise, including the demonstration that old glia migrate as far as young glia; and, 3) myelin formation in older glia required a fetal calf serum and chicken embryo extract medium, while myelin formation in younger glia could be obtained in both this medium and a semi-synthetic culture medium. The latter suggests that a difference in nutritional requirements exists between myelin formation during normal development and myelin regeneration.

Future Plans—In the present phase of this research, this team is: 1) ascertaining whether or not there is any age limit for glial cells to form myelin within the tissue culture system; 2) confirming the difference in nutritional requirements; and, 3) beginning a more refined analysis of both age and nutrition as variables influencing this regenerative behavior, aided by computerized 3-D reconstructions.

Regulation of Synthesis and Expression of Neurotrophic Agents and Neuropeptides

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Sponsor: *National Institutes of Health*

Purpose—Evidence suggests that parallel biochemical and regulatory processes occur during normal development and following various forms of central nervous system (CNS) injury. Among the areas of particular interest are: 1) the identification of CNS neurotrophic factors; and, 2) the analysis of the regulation of neuropeptide gene expression during development and in response to injury.

Progress—Studies are underway to identify tropic factors produced in two specific model systems, since recent evidence suggests that a family of nerve growth factors exists, each specific for certain populations of neurons. Mouse cerebellum contains a factor which is nerve growth factor (NGF)-like by immunological criteria, but has no biological activity on chick sensory neurons. This factor increases in the cerebellum of the pcd mutant mouse as the Purkinje cells die out and astrocytes proliferate. The mRNA for this factor appears to hybridize with mouse beta-NGF cDNA and is increased in pcd cerebellum. Screening of cDNA libraries is currently in progress, in order to clone the factor.

In another injury paradigm, multiple cortical lesions are made in rat brain: one week later, RNA is prepared from various brain regions to be analyzed for any change in NGF-like mRNA's relative to unlesioned brain.

At the same time, these injury models can be evaluated for changes in neuropeptide and/or neurotransmitter synthesis occurring in response to the lesions. One can derive as estimate of peptide turnover by combining measurements of the precursor mRNA, the precursor, and the peptide.

Future Plans/Implications—Our studies have demonstrated that peptides are differentially regulated by such chronic drug treatments as reserpine, haloperidol, 6-hydroxydopamine or 5, 7-dihydroxytryptamine. Work is in progress to determine the effects of CNS injury and recovery on various neuropeptides, as well as such neurotransmitter synthetic enzymes as tyrosine hydroxylase and glutamic acid decarboxylase (GAD).

Quantitative Studies of Nerve Regeneration

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Sponsor: *National Institutes of Health*

Purpose—This is a collaborative project with the aim of developing, validating, and applying a quantitative measure of nerve regeneration to the study of factors that promote or regulate the rate and extent of axonal outgrowth in both peripheral and central nervous tissues.

We have developed a quantitative fluorescent method based on immunochemical detection of phosphorylated neurofilament protein. The technique has been validated by applying it to a study of sciatic nerve degeneration and regeneration subsequent to nerve crush. Studies are in progress to extend this technique to studies of spinal cord degeneration and regeneration subsequent to controlled crush injury.

D. Rehabilitation

Treatment of Physiological Impotence

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B299-3RA); National Institutes of Health*

Purpose—Implementation of a plan for effective rehabilitation of sexual function in paraplegic patients has required an interdisciplinary cooperative effort among experts in rehabilitation medicine, biomedical engineering, neurology, and physiology. We have been developing and clinically testing a device to permit production of erection and semen collection through rectal probe electrostimulation (RPE). This technology has gradually become refined from a multiple-component experimental system to a compact single-unit instrument equipped with state-of-the-art electronics. Features have included constant current stimulation capabilities, plug-in modular construction, an isolation transformer, and fail-safe circuits designed to inactivate the unit when current limits are exceeded.

Progress—An important new refinement in this equipment has been the addition of a battery option to permit RPE without direct connection to the electrical mains. Also, through the use of computer-driven circuitry, consistently uniform stepwise increases in electrical stimulation can now be made. Previously, stimulus envelopes of gradually increasing intensity were created manually, with poorer repeatability. Extensive pre-testing of various RPE prototypes, using chimpanzees as animal models, increased the rapidity with which such design features could be visualized and implemented for use in the human patient setting.

Clinical testing is presently underway, and will continue in the coming year. Favorable preliminary results have been forthcoming in at least two areas. The first is increased safety and ease of operation of the device; the second is the ability to hover for short time periods around selected submaximum current levels, just below the level of patient discomfort and/or spastic lower limb activity, which are adequate for stimulating ejaculation. Our success rate of producing seminal emissions has thus risen to virtually 100 percent. This, in turn, has permitted greater opportunity to grapple with the continuing need to improve sperm motility (typically low) in collected specimens if they are to be used successfully in artificial insemination. Various techniques of rapid removal of sperm from contaminating urine (from retrograde ejaculation) and reconstituting in buffered Ringer lactate solution are being evaluated to restore the physiologic osmolality relationships so essential to sperm viability.

Alterations of Blood Rheology in Spinal Cord Injured Patients

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #B937-PA)*

Purpose—The development of pressure sores is preceded by a shutting off of blood flow in the small vessels of the skin. Since blood flow in these vessels is strongly influenced by blood viscosity, red cell rigidity, and red cell aggregation, we plan to study blood rheology (i.e., flow and/or deformation characteristics of blood and its components) in spinal cord injured patients.

Spinal cord injured patients are subjected to the risk of pressure sores because of prolonged bed rest or wheelchair confinement combined with the loss of mobility and sensation. If altered blood rheology contributes to the risk by impairing circulation in the skin, then some type of blood testing might be usable as a technique for identifying hospital patients at admission who will need additional preventive care. In addition, a role for red cell rigidity or aggregation in the tendency toward pressure sores would suggest the possibility of a degree of prevention by using selected drugs which can alter these properties.

Increases in red cell rigidity, red cell aggregation, and blood viscosity have been reported in diabetes, in certain cancers, and in other diseases involving the small blood vessels. It has also been shown that the red cell recovers its flexibility very quickly after prolonged application of external pressure to the skin of able-bodied subjects, but red cell rigidity has never been studied in spinal cord injured subjects. The high incidence of pressure sores and venous thrombosis in acute spinal cord injured patients indicates that red cell behavior may indeed be altered by spinal cord injury. Therefore, we plan to study blood rheology in spinal cord injured subjects with and without pressure sore problems and to compare those results with comparable measurements in blood samples from the able-bodied population.

It is hypothesized that spinal cord injury produces a change in the rigidity and aggregation of red blood cells, thereby increasing blood viscosity and aggregation and inhibiting blood flow in the microcirculation. If this is the case, it is expected that the tendency to develop pressure sores would be increased because less external pressure would be required to cut off blood flow, and recovery of blood flow would be impaired.

Methodology—Red cell aggregation can be observed and measured under controlled conditions by the use of a rheoscope, an instrument combining a transparent cone-plate viscometer with an inverted microscope. This instrument permits illumination, observation, and photography of red cell aggregates in motion at controlled rates of shear corresponding to conditions in the vessels of the microcirculation. A separate instrument, a metal cone-plate viscometer, is used for accurate measurement of blood viscosity. Special filters are used to determine red cell rigidity by measuring flow rates under controlled pressures with pore sizes smaller than a single red cell.

Blood will be drawn from able-bodied subjects and from spinal cord injured patients with and without pressure sore problems. The following characteristics will be measured: 1) whole blood viscosity; 2) red cell aggregation; 3) red cell deformability; 4) plasma viscosity; 5) sedimentation rate; 6) complete blood count and platelet counts, hematocrit and red cell indices; and, 7) plasma fibrinogen levels. Items 1 through 5 will be measured using a Brookfield microviscometer and a Wells-Brookfield rheoscope, as well as filtration techniques. Items 6 and 7 are periodically performed by Laboratory Services on every patient on a routine basis. Any significant rheologic differences will be detected by these measurements if they exist.

Progress—A small laboratory space has been set up within the Spinal Cord Injury Center for the study of blood rheology. Instrumentation includes a Brookfield microviscometer, a Wells-Brookfield rheoscope, water bath, incubator, and centrifuges. A horizontal filtration system has been assembled using 5 micron Nuclepore filters to determine red cell flexibility by recording pressure difference across the filter as a function of time for a fixed flow rate. The entire filtration system fits inside the incubator along with the sedimentation rack. Measurements are now in progress.

Skin Deformation and Blood Flow Under External Loading

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #B924-PA)*

Purpose—Spinal cord injured patients are more likely to develop pressure sores than are able-bodied individuals because of the loss of mobility and sensation. Some patients are more prone to such problems than others, and the reasons for these differences are not known. Since pressure sores are always preceded by a compromise of blood flow in the skin, this investigation is directed toward the measurement of skin blood flow response to external pressure loading in spinal cord patients.

There have been a limited number of studies in which skin blood flow under external loading has been measured by a number of different techniques. These findings have shown that there is a decrease in skin blood flow with loading, although there is considerable variation in the quantitative results, and blood flow in the skin apparently ceases at a local pressure loading of about 100 mm Hg in able-bodied young subjects. These occlusive pressures are evidently much lower in older paralyzed subjects. But the large variability of the curves of skin blood flow versus pressure makes it difficult to draw any meaningful conclusions. This study differs from previous studies in two major respects: first, a dimensional analysis is carried out to insure that all the necessary quantities are measured and treated in appropriate nondimensional forms to give meaningful results; and second, a relatively new noninvasive technique is used for the direct measurement of skin blood flow.

It is hypothesized that the response of skin blood flow to external loading will be found to be significantly different between those patients who do and do not develop pressure sores, provided that all of the necessary quantities are accurately measured and that the results are plotted in the appropriate nondimensional forms.

Methodology—We use cylindrical or spherical indentors combined with a laser Doppler flow meter to measure skin blood flow response to loading in able-bodied subjects and in spinal cord patients who do and do not have a continuing problem with pressure sores. Dimensional analysis has shown that percentage reduction of skin blood flow due to loading depends upon only two dimensionless variables: 1) the ratio of skin indentation to bone depth; and, 2) the ratio of indentor size to bone diameter. Measurement of pressure is not necessary, and the required measurements can be made over any bony prominence, since these results are not specific to any one site. The essential measurements are bone depth, skin indentation, and skin blood flow. These measurements are combined to produce the necessary dimensionless plots of percent blood flow reduction versus percent tissue compression.

Progress—Our earlier studies showed that the laser Doppler flowmeter does not accurately measure skin blood flow under conditions of high loadings, since instrument errors become increasingly significant as blood flow is reduced by loading. Therefore, a new apparatus has been designed to apply only small displacements of the skin while making accurate simultaneous measurements of skin displacement and skin blood flow.

Skin indentation relative to the surrounding skin surface is measured by means of four photodetectors mounted into the indentor support mechanism. Skin blood flow is simultaneously measured on a continuous basis using the laser Doppler flowmeter. In order to check this technique against traditional methods, we also intend to measure contact pressure by determining applied loads and the area of contact using photographic methods with a fluid interface. Bone depth is measured with a portable echo Doppler unit.

The photodetectors have been breadboarded, tested, and calibrated so that we are operating in a linear range of output with small displacements. The supporting mount and the spherical indentors have been machined and fabricated, and the entire system is now ready for initial testing on human subjects.

Publications Resulting from This Research

Difficulties in Laser Doppler Measurement of Skin Blood Flow Under Applied External Pressure. Sacks AH, Ksander G, O'Neill H, Perkash I, *J Rehabil Res Dev* 25(3), 19-24, 1988.

The Use of EMG Biofeedback and Functional Electrical Stimulation in Spinal Cord Injury

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Purpose—This study compared the relative effects of functional electrical stimulation (FES), electromyographic (EMG) biofeedback, and conventional therapeutic modalities (physical and occupational).

Progress/Methodology—Both male and female incomplete quadriplegics between the ages of 18 and 45 participated in this study. All subjects had cervical (C-4 to C-6) level spinal cord injuries. Each of the therapies was administered according to an individual's deficit (i.e., C-6 injuries were not trained for C-5 innervated muscles such as deltoids and biceps). Subjects were placed into one of 4 groups utilizing a restricted randomization process to prevent the loading of any of the group cells with more severe (in terms of deficit) injuries. All subjects were at least one year post-injury.

The groups differed on the basis of therapies provided over the 16 weeks of training. The training period was divided into two consecutive 8-week time blocks. During each of these time blocks, subjects were administered one, and only one, of the following therapies: 1) conventional physical/occupational therapy (PT/OT) consisting of upper extremity strengthening, mat mobility, and wheelchair skills training; 2) FES of the muscles of the upper extremity. The muscles stimulated were the biceps, triceps, wrist flexors, and wrist extensors. Stimulation was provided bilaterally so that a total of 8 muscle groups were stimulated; 3) EMG biofeedback was provided for the same muscle groups. A Neuropath 4,000 EMG Biofeedback training machine was used. Recording electrodes were placed over each of the 8 muscles previously described. The electrical signals produced by the individual muscles were displayed on a color television monitor. An audio signal was also provided. At any time, the signal from the muscle being worked was displayed as well as its opponent muscle (e.g., wrist flexor-wrist extensor). Subjects were instructed to try to maximize the amplitude of the signal for the muscles being trained.

Group One consisted of 10 subjects (7 male, 3 female), who each received biofeedback for the first 8 weeks of training and PT/OT for the second 8 weeks. Group Two consisted of 10 subjects (8 male, 2 female), who received biofeedback training for the first 8 weeks and FES for the second. Group Three consisted of 9 subjects (8 male, 1 female), who received FES training for the first 8 weeks and PT/OT for the second. Group Four consisted of 10 subjects (8 male, 2 female), who received PT/OT during the entire 16 weeks of training.

Baseline measures on all of the dependent variables were obtained during the week prior to the initial training period. The same measures were assessed after the first 8 weeks of training and then after completion of the 16 weeks of training.

The dependent measures obtained to test study hypotheses were: manual muscle test scores; Self-Care Ability scores; voluntary EMG activity measured in microvolts; and a mobility-performance score.

Muscles tested were: biceps, triceps, wrist flexors, and wrist extensors. Each muscle was scored on a 0-10 point scale recommended by Trombley. For statistical analyses, the scores for the 4 muscles of the left and right arms were summed separately. Thus, the score for either arm could range from 0-40. The left and right arms were analyzed separately due to the asymmetrical level of function of the volunteers used in the study.

The self-care measure consisted of a battery of sub-tests containing items relating to: feeding, hygiene, and dressing. The entire test contained 26 items and a potential score range of 0-104.

The mobility measure consisted of the summed scores of performance evaluations on transfers, mat mobility, and wheelchair skills. The possible score range was 0-100.

Muscle electrical activity was measured using the Neuropath 4,000 EMG biofeedback machine. Individual muscle EMGs were summed and divided by the number of muscles assessed to yield a mean

EMG score for each side. The mean EMGs were used in the statistical analyses.

Statistical analysis was performed with the Statistical Package for the Social Sciences Version X (SPSSx) multivariate analysis of variance (MANOVA) computer program. The analysis included a four between-groups design based on the four distinct therapy combinations received across the 16 weeks of training, with a 3-level repeated measures component.

Results—The results failed to provide any evidence of differential efficacy of the combination of therapies employed in the study to provide functional improvements. However, a statistically significant difference was found across time for all of the functional measures. The mean scores on each of the measures of functional activity improved across the 16-week time period. Considering that all of the participating volunteers had long-term injuries (i.e., greater than one year), this finding warrants a further look at providing an additional formal rehabilitation program. Since the study population included only long-term injured, it can reasonably be assumed that the improvements were not related to spontaneous recovery. Rather it must be concluded that a later-stage rehabilitation program can result in improved functional ability

Interactive Videodisk Training for Self-Care Skills

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Purpose—Instruction in self-care skills is an essential component of the rehabilitation of persons with spinal cord injuries. The importance of this component is evidenced by the fact that between one-third and one-half of spinal cord injured persons are rehospitalized in any given follow-up year. The average annual cost for each rehospitalization can range from $6,700, if surgery is not required, to $20,000, if surgery is required. The personal cost of these skills can reduce the incidence of rehospitalization due to preventable complications and hasten people's progress toward adaptation to their disability and personal independence.

Traditional methods of health-care education, such as personalized instruction by a health-care professional, self-instruction from written or audiovisual materials, participation in learning groups, or interaction with other disabled persons are often ineffective. Factors such as the person's psychosocial, economic or educational status; the extent of involvement by health-care professionals; and the instructional material or methods can all influence an educational program's outcome. Although some of these factors can be controlled and improved, others cannot. Accordingly, health-care institutions are faced with the difficult problem of teaching valuable skills to people with diverse socioeconomic backgrounds, attitudes and skills, using staff who may have little time to teach them.

We believe that this problem may be resolved by augmenting traditional education programs with interactive learning technology. Technologies such as computer-assisted instruction (CAI) or interactive-videodisk instruction (IVI) have several advantages as adjuncts to traditional educational methods. People with diverse socioeconomic and educational backgrounds can learn at their own pace. The novelty of interacting with a computer may provide motivation for learning. CAI or IVI may also be more effective than personalized instruction for teaching difficult or emotion-laden subjects, since they are impersonal and non-threatening. Interactive learning technologies also free staff to give personalized instruction to people who need it.

Our project will examine the effectiveness of interactive videodisk instruction as a supplement to two traditional rehabilitation education programs. We will develop interactive videodisk material for instructing spinal cord injured persons on self-care techniques for skin care, genitourinary care, wheelchair transfers and assertiveness. We will also develop and test instruments for evaluating the effectiveness of interactive education in terms of instruction (extent and recency of instruction), cognition (aggregate knowledge of self-care skills), and performance (current practice of self-care skills). We will determine the usefulness of interactive videodisk instruction by comparing the index scores of people who have received traditional instruction and people who have received a combination of traditional and interactive videodisk instruction. We will also develop authoring software that represents an improvement over existing software.

Implications—The software will allow users to develop interactive learning sequences that incorporate motion video, overlay graphics and questions. Our study could help spinal cord injured persons by improving the instruction they receive in order to learn the knowledge and skills they need to lead productive lives and achieve greater independence.

Clinical Evaluation of an External Urine Collection Device in Non-Ambulatory Incontinent Women

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Purpose—Urinary incontinence in females is a distressing social affliction and a complicated management problem for health care providers which is commonly managed with absorbent products or indwelling urethral catheters. Absorbent products are inconvenient and associated with objectionable urine odor. Chronic use of indwelling urethral catheters invariably results in polymicrobic bacteriuria. An external device that captures the urine stream and directs it into a collection vessel effectively, without adverse complications, may have an important impact on medical care costs and patient comfort, and may reduce catheter-associated urinary tract infections associated with chronic indwelling catheter use.

Progress—We have entered into collaborative studies with device manufacturers to facilitate development and clinical evaluation of external urine collection devices for women which would be analogous in function to the condom catheter for men.

We have clinically evaluated the performance of an external urine collection device for women (Female Urinary Pouch, Hollister, Inc., Libertyville, IL) for 10 consecutive days on two patients, and 21 consecutive days on five patients. The pouch is a flexible plastic device which funnels urine into a bedside collector and is secured to the patient with an adhesive similar to that used on ostomy appliances. All patients had a history of chronic urinary incontinence managed by absorbent products. Each pouch was allowed to remain *in situ* for a maximum of 48 hours. Assessment included effectiveness of the pouch to collect urine without leakage, periurethral irritation or discomfort to the patient.

Results—We evaluated 63 applications of the pouch for 125 patient-days in seven women. Efficacy and adverse reactions were recorded every 12 hours of continuous usage. Through 24 hours of continuous device usage, only eight of 63 devices (13 percent) leaked urine, and only two of those (3 percent) in sufficient quantity to require replacement. Between 24 hours and 36 hours of continuous device usage, urine leakage was detected from 12 additional devices, but only two required replacement. Between 36 hours and 48 hours of device usage, 11 additional devices leaked urine; five required replacement. Thus, at 48 hours only nine of 63 pouches (14 percent) required replacement due to unacceptable leakage. Periurethral reactions were minimal. At removal of two pouches, erythema was noted and in both cases was 1+ (slightly red mucosa). One was the first of five pouches applied on a patient who continued to wear pouches for 10 days, the second was the first of 10 pouches applied on a patient who continued to wear pouches for 21 days. Neither patient had erythema when any subsequent pouches were removed.

In one patient, periurethral reaction was noted following the removal of the second, fifth, and sixth of 10 pouches applied. This patient wore pouches for 21 days; edema was not present at the conclusion of the study.

Implications—Results from this preliminary evaluation suggest that external urinary collection devices for women held *in situ* by adhesive similar to that used on ostomy appliances may provide a useful alternative to other methods of chronic urinary incontinence management in non-ambulatory women. Additional studies for a longer, more clinically-relevant period appears to be warranted. Once long-term efficacy is established, the impact of external device use on complications associated with currently available methods of chronic urinary care can be investigated.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: Part 1, Dermal Blood Flow Measurements via Technetium-99m Pertechnetate Clearance

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Purpose—Pressure sores (decubitus ulcers, ischemic ulcers, etc.) represent a severe and costly problem for many disabled individuals. This is particularly true for those who are wheelchair dependent and have sensory loss. A research program has been implemented to determine whether electrical muscle stimulation (EMS) can be used to prevent the formation of pressure sores. Pressure sore etiology is a complicated event involving many parameters, but most investigators agree that a primary event leading to pressure sore formation is blood flow occlusion. Occlusion of lymph flow and disturbance of interstitial fluid flow are also important factors. The current study investigates the effects of EMS on tissue blood flow.

The scope of the current project is to investigate those "immediate/dynamic" effects of EMS for preventing pressure sores. One of the hypothesized mechanisms whereby EMS may be effective is that tissue undulation and variations in the seating interface pressure will permit increased blood flow. Previous work in this area has shown that EMS of the gluteus maximus muscle can produce substantial interface pressure variations, tissue undulations, and appreciable shape reconfiguration of the buttocks under load. These are true even at low stimulation intensities easily tolerated by sensate subjects. It has also been shown, using intramuscular injections of xenon-133, that EMS can produce an increase in muscle blood flow of the gluteus maximus under load.

Progress—Skin blood flow studies were performed on 8 SCI subjects. All subjects had a complete sensory and motor paralysis at or above the T_{10} level. None of the subjects had a history of surgery due to pressure sores under the ischial tuberosities (IT). Bilateral stimulation of the gluteus maximus muscle was performed using surface electrodes and a commercially available neuromuscular stimulator. Subjects were positioned in a seat designed to simulate a standard wheelchair seating position. A pressure monitoring system was used to record and monitor stimulation intensity by measuring changes in seating pressure distribution during EMS.

Skin blood flow was measured via intradermal injections of technetium-99m pertechnetate (^{99m}Tc) at the site of each IT. Sequential scintigraphic images of the injection site were recorded throughout the trial with a gamma camera. Following imaging, a time-activity semilogarithmic plot of the ^{99m}Tc washout was obtained where the slope is proportional to the blood flow. A skin inspection which was performed following the test protocol revealed that of the eight SCI subjects tested, only five injection sites proved to be within the area of redness induced at the ischial tuberosity as a result of sitting. In addition, for one of the subjects, the

EMS intensity was set too low to induce any noticeable movement. Therefore statistical analysis was performed on only 4 sets of data. A paired t-test was performed to compare the average blood flow during the rest period before stimulation with blood flow during the two minutes of EMS. Although no statistically significant difference was found, in all cases there was increased blood flow during EMS.

Future Plans—Measurement of skin blood flow is an important part of evaluating the potential efficacy of EMS for pressure sore prevention. However, due to the problems encountered using radioactive tracer injections, laser Doppler flowmetry is being pursued as an alternative means for measurement of skin blood flow. Part 2, which follows, describes this technique. Clinical trials to directly determine the effect of EMS on skin condition while sitting are also in progress. Part 3, which also follows, describes this experiment.

Publications Resulting from This Research

Ischial Blood Flow of Seated Individuals During Electrical Muscle Stimulation. Levine SP, Kett RL, Wilson BA, Cederna PS, Gross MD, Juni JE. *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:642-643, 1987.

Ischial Blood Flow in the Skin of Seated SCI Individuals During Electrical Muscle Stimulation. Kett RL, Levine SP, Wilson BA, Gross MD, *Proceedings of the ICAART Conference*, Montreal, 324-325, 1988.

The SPIRAL Pressure Monitor. Jaros LA, Levine SP, Kett RL, Koester DJ. *Proceedings of the ICAART Conference*, Montreal, 308-309, 1988.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: Part 2, Dermal Blood Flow Measurements via Laser Doppler Flowmetry

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Purpose—Measurements of skin and muscle blood flow are important parts of determining the efficacy of electrical muscle stimulation (EMS) for the prevention of blood flow. Previous reports have documented a significant increase in the muscle blood flow resulting from EMS. Part 1 of this 3-part report described a technique for measuring skin blood using intradermal injections of ^{99m}Tc. Due to difficulties encountered using this technique, laser Doppler flowmetry is now being pursued for measurements of skin blood flow.

Laser Doppler flowmetry offers several advantages over the radioactive tracer injection technique: 1) Placement of the fiber optic probe can be made after the subject has been sitting so that blood flow measurements over the ischial tuberosities or other specific areas of high pressure are ensured; 2) It is a noninvasive procedure; 3) Real-time results are available; 4) The required sampling duration is much shorter; 5) Positioning of the subjects should not be a problem because they will be able to sit in their own wheelchairs; and, 6) All of the equipment is portable and can be used in various settings.

Progress—Skin blood flow at the ischial tuberosity (IT) during EMS is being measured via laser Doppler flowmetry. All subjects for this study have a complete sensory and motor paralysis at or above the T_{10} level and no history of pressure sores at the IT. A flat dermal probe (0.1 inch thick) is placed between the subject's IT and the seat cushion and surrounded by a small contoured pad. Placement of the probe is determined by first having the subject sit on a hard surface to induce erythema at the IT. The location is marked and then EMS surface electrodes and the laser Doppler probe are placed while the subject is prone. Subjects then sits upright on a flat foam cushion in the wheelchair.

EMS is applied using a commercially available stimulator. Stimulation protocols are being investigated to determine an optimal procedure for skin blood flow. Adjustments include frequency (3-50 Hz), duty cycle, and amplitude. Amplitude is set according to interface pressure changes induced.

Preliminary Results—To date, six different subjects have been tested with a variety of EMS protocols.

Although no statistically significant results have been found, several of the experimental protocols have demonstrated promising results.

Future Plans/Implications—Skin blood flow measurements as described here will continue with the expectation of optimizing the EMS protocol used. In addition, transcutaneous oxygen tension measurements are planned in an effort to determine a more direct effect of EMS on tissue viability. Ultimately, once the optimal EMS parameters are determined, they can be implemented in the clinical trials which are currently in progress and described in Part 3 of this report.

Electrical Muscle Stimulation for the Prevention of Pressure Sores: Part 3, Clinical Studies

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Purpose—Clinical trials provide a basis for testing the efficacy of the immediate/dynamic effects of electrical muscle stimulation (EMS) for preventing pressure sores. The experimental design described permits clinical investigation of the efficacy of EMS previous to larger scale clinical trials which are subsequently planned.

Progress—Subjects for this study have an acute onset of motor and sensory complete spinal cord injury (level of T_{10} or higher) of less than 6-months duration. All subjects are inpatients of the University of Michigan Spinal Cord Injury Service. The study consists of two parts. The first part involves the establishment of a "safe skin sitting time" (SSST). Subjects are not allowed to perform any pressure relief activities during sitting. The SSST is defined as the sitting time at which the subject develops an area of erythema which persists for at least one hour following sitting.

The second part of the study is carried out after the SSST is established. A time series experimental design (A-B-A-B) is applied. Phase A involves sitting for the SSST with no EMS; Phase B involves sitting for the SSST with EMS. EMS is provided via surface electrodes and a commercial stimulator. The EMS parameters are based on results from previous experiments.

Following sitting, a visual skin inspection and a thermographic evaluation are made. The graded skin inspection is performed immediately following sitting and one hour later. The thermographic evaluation involves the monitoring of the skin temperature at the area of redness and the surrounding area for one hour following sitting.

Preliminary Results—Preliminary trials with three subjects have been performed. Problems have been encountered with muscle fatigue over the course of the SSST. This has been mostly due to the use of continuous stimulation paradigms as opposed to intermittent ones. To counteract this problem, a stimulator is being modified to provide stimulation duty cycle parameters appropriate for this study.

Future Plans—The experiment will be performed on a minimum of 10 subjects. Results from this study will be used to initially assess the clinical efficacy of EMS for preventing pressure sores and to determine the appropriateness of planned trials with a large population of outpatients.

Early Detection of Pressure Sores by Means of Biomedical Indicators

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Purpose—Pressure sores are a serious secondary problem for many people with disabilities and often result in prolonged periods of hospitalization or bed rest. If a simple and reliable method for detecting the early onset of a pressure sore could be provided, health care providers and individuals at risk for developing pressure sores could intervene early-on and either prevent or limit frank breakdown.

Significant biochemical changes in tissues are thought to be associated with the early onset of pressure sores. Basic studies investigating tourniquet effects and compartment syndrome indicate that biochemical changes in tissues associated with cell necrosis can be detected after less than 40 minutes of ischemia. If such sensitive biochemical changes could be measured in a clinically practical way, then they offer hope for early detection or screening for tissue distress.

One of the cellular constituents released when cells undergo ischemia-induced necrosis is creatine kinase (CPK). Elevated serum CPK can be readily detected in patients following myocardial infarction. Total serum CPK can be separated into fractions representing derivatives from cells in the brain, heart and skeletal muscle. Measurement of the skeletal muscle derivative offers promise for detecting trauma associated with the early onset of a pressure sore. Measuring serum CPK offers a possible systemic method for detecting tissue damage, but additional tests would be beneficial to localize areas of damage. Invasive sampling of tissues is unacceptable clinically and, therefore, methods for transcutaneous tissue analysis are required. In this study, the potential for detecting biochemicals associated with adverse tissue reactions transported from the tissues in sweat is being investigated.

Progress—Serum CPK has been measured in a group of 6 pigs subjected to localized indentation over bony prominences for a duration of 6 hours. Marked elevations of serum CPK were detected immediately following the removal of the indentors and were sustained for up to one week prior to sacrifice. Histological evaluation of the tissues demonstrate areas of tissue damage that were not severe enough to ulcerate, but were sufficient to significantly elevate serum CPK.

With the concept of measuring serum CPK demonstrated in the animal model, a clinical study has commenced in patients known to be at risk for developing pressure sores. To provide a baseline, all participating subjects are screened for serum CPK and the skin condition carefully documented. Inpatient participants are then monitored for any evidence of persistent redness or other adverse tissue responses. In the event that an adverse response is detected, a second serum sample is taken for CPK analysis.

Analysis of local biochemical changes is being undertaken using a commercially available technique to induce sweating. Currently, interest is focused on histamine as a possible mediator of the inflammatory response normally associated with a Stage I pressure sore (persistent redness).

Future Plans—At present, the role of histamine in this response has not been confirmed. A preliminary study is therefore underway inducing histamine in skin by producing a mild inflammatory response to ultra-violet light. Sweat induction will be undertaken 8 hours post-irradiation when histamine concentration is known to be at maximum. If histamine is found to be transported by sweat in measurable concentrations, then the sweat collection technique will be applied to patients with a State I pressure response, thereby determining whether histamine plays a significant role in this inflammatory response.

Publications Resulting from This Research

Biochemical Changes in Sweat Following Prolonged Ischemia. Ferguson-Pell MW, Hagisawa S. *J Rehabil Res Dev* 25(3):57-62, 1988.

Exercise Hemodynamics of Quadriplegics: A Pilot Study

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Purpose—The purpose of this pilot study is to assess the acute central and peripheral hemodynamic adjustments of spinal cord injury (SCI) quadriplegic patients to incremental arm-crank exercise (ACE) and to prolonged bouts of submaximal ACE in two postures (sitting and supine) representing two different orthostatic loads. Specifically, this study is designed to: 1) separate the hemodynamic effects of posture and exercise; 2) assess the effects of postural change on exercise capacity; 3) study physiologic mechanisms which may improve blood flow to active muscles in quadriplegics during arm exercise; and, 4) determine the extent to which postural stress contributes to hypokinetic circulation in quadriplegic subjects during arm exercise.

Progress—Ten SCI quadriplegics are currently engaged in the following testing protocols: graded submaximal and maximal ACE tests in sitting and supine postures, prolonged ACE tests at 70 percent $\dot{V}O_2$max in sitting and supine postures, and 45-minute resting tests in each posture. ACE is performed with an electronically-braked cycle ergometer mounted appropriately for arm-cranking. Metabolic, pulmonary, and hematologic status are monitored with continuous open-circuit spirometry and periodic arterialized capillary blood sampling. Central (cardiac) and peripheral (right calf) hemodynamic assessments are made at regular intervals with impedance cardiography and plethysmography, ECG, and auscultation.

Preliminary Results—Initial results from six subjects indicate that, compared with upright sitting, the supine posture elicits higher mean maximal ACE power output (by 14 W, +32 percent), oxygen uptake (by 0.25 L/min, +30 percent), cardiac output (by 2 L/min, +26 percent); pulmonary ventilation (by 8 L/min, +16 percent), heart rate (by 12 bpm, +10 percent), and stroke volume (by 8 ml/bt, +12 percent). Mean peak values of arterial blood pressures decreased by 5 mmHg (−6 percent), while arteriovenous O_2 difference was identical for each posture. To date, all subjects have been able to perform 45 minutes of prolonged ACE at 70 percent of their posture-specific $\dot{V}O_2$max. These data suggest that the upright posture impairs circulation during ACE in quadriplegics and may be responsible for the "hypokinetic" circulatory responses to arm exercise reported in the literature. The supine posture appears to improve the central circulatory response to maximal ACE in quadriplegics. Possible mechanisms for improved performance include prevention of venous pooling in the legs, facilitated venous return and cardiac preload, reduced cardiac afterload, increased sympathetic tone and myocardial performance, and enhanced blood flow to exercising arm muscles. Higher cardiac output (blood and O_2 delivery) appears to support higher levels of aerobic metabolism and work capacity.

Future Plans/Implications—Central circulatory responses and arm exercise capacity of quadriplegics appear to be highly dependent upon posture. Present results suggest that, in SCI quadriplegics, supine ACE may be superior to upright ACE as a mode of aerobic training based upon the greater metabolic and cardiopulmonary responses elicited. Future research needs to address this hypothesis.

Lower Extremity Spasticity Following Spinal Cord Injury

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B320-RA)*

Purpose—Spasticity represents hyperactive spinal reflexes, and such exaggerated reflexes commonly develop caudal to a spinal cord injury (SCI). This spasticity can impair positioning and voluntary movements, thus interfering with patient function and contributing to decubiti. This study examines the lower extremity manifestations of SCI spasticity and describes the time-course of the appearance of this hyperreflexia over the first year post-SCI.

Progress—Serial clinical and electrophysiologic studies have been undertaken in acute and chronic SCI subjects with complete injuries. Tibial and femoral H reflex excitability, measured as H/M amplitude ratios, tend to increase during the first 3 months post-injury, although M response amplitudes decrease initially, and then often increase as spasticity becomes more apparent. Tendon reflexes also increase in excitability over time, although initially they are absent when H reflexes are readily elicitable. Flexor withdrawal reflexes, recorded in the biceps femoris and tibialis anterior muscles to electrical stimulation of the sural nerve, tend to be of larger amplitude and lower threshold in chronic, as compared to acute, SCI subjects.

Results—In chronic SCI, hyperactive tendon reflexes, clonus and extensor spasms are often seen together. Spontaneous flexor spasms and triple flexion response with plantar stimulation of the foot commonly appear together. Those with incomplete spinal cord injuries note more functional limitations due to their spasticity than do those with complete cord injuries. Those with quadriplegia and complete cord injuries report more functional use from their spasticity than do those with paraplegia and incomplete injuries.

Future Plans—Future studies will examine reflex changes in incomplete SCI subjects and the effect of motor recovery on those changes.

Publications Resulting from This Research

Spasticity and Associated Abnormalities of Muscle Tone. Little JW, Merritt JL, In *Principles and Practice of Rehabilitation Medicine,* JA DeLisa, et al. (Eds.), Philadelphia: J.B. Lippincott Co., 430-447, 1987.

Motor Recovery in the Absence of Segmental Afferents: A Case Study of Incomplete Spinal Cord Injury. Little JW, Harris RM, Smithson D, *Paraplegia* (accepted for publication).

The Bent-Finger Technique for Studying Skin Biomechanics Related to Pressure Sores

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Sponsor: *VA Rehabilitation Research and Development Center Core Funds*

Purpose—The response of skin blood flow to external pressure loading is believed to be related to the tendency to develop pressure sores. The study of this response ordinarily involves the use of rather sophisticated instrumentation for the measurement of blood flow. A much simpler technique is explored here which involves the whitening of the knuckle in a bent finger.

The central hypotheses of this project are that: 1) the skin blood flow of subjects who are prone to developing pressure sores will show a response to pressure loading which differs significantly from that of subjects who do not; and, 2) this difference can be detected by using simple controlled measurements and observations of the bent finger.

Progress/Preliminary Results—We have made preliminary measurements of skin elongation using a finger goniometer. Some of our data have shown considerable scatter, presumably because the elongation measurement technique is not highly accurate. Nevertheless, the dimensionless ratio of pressure to elastic modulus at blood flow occlusion was found to be significantly lower in the paraplegics tested than for the able-bodied population.

This result means that a much lower pressure would be required to occlude capillary blood flow in paraplegics with the same skin elasticity. We also found significant differences for the values of skin elongation at occlusion between the two groups, which may allow us to screen patients without the need to make the ultrasound measurements at all.

Future Plans—Because of inaccuracies in the elongation measurement technique employed initially, and because only 9 able-bodied subjects and 6 paraplegics have been tested to date, we plan to make use of a Pentax ME Super 35Pmm camera and to design a camera and lighting mount which will accept the hand in a fixed position. This will enable us to take pictures of the bent finger under controlled conditions without contact of the dorsal skin surface. These pictures will be digitized for application of a curve smoothing program from which more precise and consistent measurements of skin elongation can be obtained.

Publications Resulting from This Research

Skin Response to Pressure Loading by the Bent Finger Technique. Sacks AH, O'Neill H, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:302-304, 1987.

Pressure Sore Assessment Utilizing Nuclear Magnetic Resonance (NMR) Imaging and Spectroscopy

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Sponsor: *VA Medical Center, Castle Point, NY*

Purpose—Our study hypothesizes that NMR measurements can provide early warning of impending tissue ulceration. The extent to which NMR can provide sensitive detection of tissue damage is being examined.

Methodology—Pressure sore and uninvolved tissues have been imaged. High resolution spectroscopy was separately utilized to analyze patient samples. Also studied by high resolution spectroscopy were samples of ischemic and necrotic tissue from a canine surgical flap, and phosphorus analysis was also done. We have sought to identify parameters for NMR analysis which result in greatest sensitivity to developing pressure sores or to the healing process.

Progress—*High Resolution Spectroscopy.* Large differences are seen in the ratio of fat to water among samples. Therefore, NMR imaging and analysis should use data acquisition parameters which will separately account for water and fat. The water peak width varied from one-half to 2 ppm in high resolution studies. A narrower width occurred with subcutaneous pressure which might be expected as a sample loses the structure of healthy tissue. Most currently available imaging systems do not have the frequency resolution to detect these observed differences, but may as the technology develops further.

NMR parameters for both proton and phosphorus analysis were determined. Since large changes occur in phosphorus after tissue death, we obtained the parameters for the spectrum after tissue death as a benchmark for future studies.

Proton T1 and T2 relaxation parameters were determined for water and fat peaks in the samples. Differences in T2 for both fat and water were associated with narrower peaks.

Imaging. Large differences in image appearance were seen among samples. The encouraging aspect is that NMR can detect differences among different samples. The challenging aspect is to relate the changes to differentiation between healthy and diseased tissue. In order to better compare sample images, we have turned to gray level transformations in which the image intensities are adjusted.

Implications—From the large differences among samples in both spectra and images, we anticipate that NMR is sensitive to pressure sore-related differences in tissue. Since large changes occur in the fat-water ratio, this must be included as a factor in NMR analysis. If NMR analysis should continue to prove useful in detecting pressure sore onset or healing processes, then its use would be justified in predicting the need for an increased or reduced number of days of therapy.

Wheelchair Graded Exercise Test for Patients with Lower Limb Disabilities

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Sponsor: *Rehabilitation Research and Development Center, Edward Hines, Jr. VA Hospital; Paralyzed Veterans of America (Vaughan Chapter)*

Purpose—Wheelchair locomotion, even under ideal environmental conditions, can result in elevated levels of exertion and fatigue. For some elderly persons, and patients with cardiovascular and/or pulmonary impairments, manual wheelchair locomotion may pose a significant health risk. If health care professionals must make judgments regarding a patient's capacity to endure the exertional stress of operating a manual wheelchair, give exercise prescriptions for rehabilitation and/or develop aerobic conditioning regimens, they must have appropriate measurement tools for patient evaluation. Therefore, the purpose of this research project is to develop improved methods for objective evaluation of the cardiorespiratory health and fitness of spinal cord injured (SCI) and other patients with lower limb disabilities. The objectives of this research are to: 1) establish standardized maximal and submaximal wheelchair graded exercise tests to accurately measure the cardiorespiratory fitness of patients who are restricted to the manual wheelchair; 2) evaluate the sensitivity of the testing system for detecting abnormal cardiovascular and pulmonary responses to exercise stress in SCI and other persons with lower limb disabilities; and, 3) compare wheelchair experimental testing protocol test data against data obtained from conventional arm crank ergometry.

Progress—New experimental continuous and discontinuous wheelchair graded exercise test protocols that are specific to the operating characteristics of the Wheelchair Aerobic Fitness Trainer (WAFT) have been designed and are now being utilized. These tests are analogous to the well-established procedures for lower limb exercise testing. Because the intensity of exercise on the WAFT can be controlled, it is possible to test patients with very low to very high exercise tolerance.

We have completed several bench test experiments on the WAFT. A standard wheelchair with a 73 kg rider was placed on the WAFT and a variable speed motor used to rotate a wheelchair wheel. A Lebow strain gauge rotating shaft torque sensor in line with the motor and wheel was employed to establish the power requirements for pushing the wheelchair wheels at various resistance settings and speeds. Findings from these experiments have resulted in: 1) modifications in the magnetic braking device to make it more suitable for our research purpose; and, 2) power output requirements at different stages in the graded exercise test protocols have been established.

Cyclocomputers have been replaced by electronic tachometers that give the user continuous visual feedback regarding the speed of both wheelchair wheels (resistance and speed of each wheel may be manipulated independently on the WAFT). A computer printout of the speed of each wheel during the various stages of the test is also available, thereby providing more precision in the determination of each subject's power output during the exercise test.

Implications—These evaluation procedures will provide baseline data useful in judging the effectiveness of patient rehabilitation and cardiorespiratory training programs, as well in charting any progressive deterioration of health resulting from disability-imposed inactivity. Exercise tests administered on the WAFT, in accordance with the established protocols, can provide valid and clinically useful information regarding the locomotor performance capacity and cardiorespiratory fitness of SCI patients and others with lower limb disabilities.

Publications Resulting from This Research

Development of a Wheelchair Aerobic Fitness Trainer for Individuals with Spinal Cord Injury. Langbein WE, Kynast L, Robinson CJ, Wurster RD, Bolam JM, Dunlap B, *American Paraplegia Society*, Las Vegas, NE, 1987.

Development of a Wheelchair Aerobic Fitness Trainer. Langbein WE, Kynast L, Robinson CJ, Wurster RD, Bolam JM, Dunlap B, *Proceedings of the Tenth Annual RESNA Conference*, San Jose, CA, 7:331-332, 1987.

Clinical Considerations Regarding the Penile Implant in Patients with Spinal Cord Dysfunction

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Erectile dysfunction is prevalent in the spinal cord injury (SCI) population as well as in numerous other males with various forms of spinal cord dysfunction. For patients who do not find alternatives to penile-vaginal intercourse acceptable, the inability to achieve and maintain an erection may be devastating in terms of self-esteem and overall sexual relationship. While surgical and mechanical success rates for penile implants are relatively high, there have been few attempts to rigorously examine SCI patient/partner satisfaction and behavioral changes following implant surgery. Additional study is required to assess these parameters, since clinicians will continue to be confronted with the question of whether the costs and attendant risks (infection, erosion) of such surgery are warranted. Objectives of this study include: 1) determination of the level of sexual satisfaction pre- and post-operatively in patients and their partners; 2) assessment of the sexual behavior pre- and post-operatively in patients and their partners; and, 3) documentation of postoperative incidents of mechanical and/or medical complications.

Methodology—SCI patients seeking treatment for sexual dysfunction will undergo a comprehensive psychological evaluation that includes the Minnesota Multi-Phasic Personality Inventory (MMPI). Subsequently, they will be assigned randomly to a penile prosthesis or psychological counseling modality for study purposes. MMPIs and other appropriate psychological profiles will be acquired at 3-month intervals. Ultimately, patients assigned first to the psychological counseling modality will be permitted to proceed with a penile implant after 3 months follow-up.

Preliminary Results—The basic protocol has been extended to include not only implants, but also the more recently available injection procedures. SCI males are increasingly opting for this less-invasive procedure over the more traditional implant approach and it will be of value to assess changes in sexual behavior and satisfaction as a result of this newer approach as well. Seven SCI persons and their partners have been entered into the injection program to date.

Future Plans—We will continue to recruit men and their partners for both the implant and injection treatments and collect data from participants pre- and post-treatment.

Psychosocial Adjustment of Persons with Combined Spinal Cord Injury and Closed Head Injury: A Longitudinal Investigation

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Purpose—Spinal cord injury (SCI) is often the result of a rapid deceleration event and/or a direct impact to the head, neck, or trunk. Therefore, in some cases, an associated closed head injury (CHI) is sustained in addition to the SCI. While evidence of a concomitant closed head injury is at times quite apparent, at other times "softer" signs of a CHI may not be so apparent and may be overlooked. This project is an attempt to determine: 1) whether persons with concomitant CHI in addition to SCI experience more marital/familial distress post-discharge than a matched group of patients with SCI only; 2) whether persons with concomitant CHI in addition to SCI achieve less progress educationally and/or vocationally post-discharge than a matched group of patients with SCI only; 3) whether persons with concomitant CHI in addition to SCI experience more psychological/behavioral distress post-discharge than a matched group of patients with SCI only; and, 4) whether persons with concomitant CHI in addition to SCI experience more social maladjustment post-discharge than a matched group of patients with SCI only.

Methodology—We will compare the social, vocational, psychological, and familial adjustment, over time, of a cohort of persons with SCI and concomitant CHI and a matched control group of persons with SCI only.

Preliminary Results—We have identified the SCI/CHI cohort and matched SCI-only controls. Twenty-one subjects were matched on length of time post-injury, neurologic level and extent of lesion, sex, race, and years of education. We are currently in the process of statistically analyzing these data and will subsequently prepare our findings for dissemination.

Comparison of Treatment Approaches in the Management of Central Cervical Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study was to compare central spinal cord injured (CSCI) patients whose cervical spines were stabilized using a halo vest versus a collar, with respect to the following outcome variables: length of hospital stay, time to ambulation, time to functional hand use and performance of activities of daily living.

Progress—The charts of 43 patients were reviewed. Patients were grouped according to treatment received and comparisons made. A random sample of the patients was interviewed and examined to see if there was any difference between the treatment groups in terms of function several years after injury. Eighteen patients were visited at home and tested for hand function, ADL, pain, fatigue and occupational performance. We also asked about vocational activity, bladder and bowel function, and ambulation.

Results—The results indicated that there were no statistically significant differences between the two treatment groups in terms of the outcome variables. The group treated with the halo vest did somewhat better (but the difference was not statistically significant). Closer examination revealed that the halo group was younger than the collar group.

Since many of the patients received surgery, the patients were reallocated to two different groups: those who had surgery and those who did not; the effect on the same outcome variables was reexamined. There was a statistically significant difference between the groups. The patients who had surgery did better than those who did not. Again, closer examination revealed that the difference was accounted for by age.

There were some statistically significant differences between the halo and collar groups as follows: on the Multidimensional Plan Inventory (MPI) the collar group reported experiencing more pain than the halo group ($p<0.005$); the MPI also revealed that the spouses of the persons in the halo group responded to their pain displays with more punishing responses than did the spouses of the collar group ($p<0.005$). The Occupational Performance History Interview revealed statistically significant differences for both groups ($p<0.005$) in adaptation to daily life before and after injury. However, there were no differences with regard to ambulation, bowel and bladder function, hand function, and ADL. These results must be viewed with caution because we had a small sample size.

Future Plans/Implications—The results of the study bring to light the fact that patients with CSCI do reasonably well whatever the initial treatment. However, fatigue and pain are chronic problems and the injury has resulted in major problems in adaptation to daily life for all patients.

The remainder of the original 43 patients will be visited and tested using the test battery to examine hand function, ADL, pain, fatigue and occupational performance, vocational activity, bladder and bowel function, and ambulation.

Identification and Evaluation of a Comprehensive Skin Care Program to Prevent Skin Breakdown in Spinal Cord Injured Patients

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Purpose—Approximately 5 percent of all persons with spinal cord injury suffer from recurrent pressure sores. While this may be considered a small number of people, the cost is extremely high both in terms of suffering, inconvenience, and finances. The purpose of the study is to identify and evaluate a comprehensive skin care education program to prevent recurrent skin breakdown in patients with spinal cord injuries. A further purpose is to evaluate two methods of gaining the subjects' cooperation in practicing skin protection behaviors.

Progress—A core skin care education program and a workbook have been developed for use with the subjects. This book, *Your Skin: An Owner's Manual,* is written at the Grade 6 reading level. The text is presented in small chunks, and it is liberally illustrated with line drawings and photographs. As a workbook, it provides space for the individual to fill in specific personal information and includes review questions at the end of each section.

To date, 24 subjects have entered the study. All receive comprehensive nutritional and psychological assessment as well as a thorough history of life since the injury, including specific details about the wheelchair and cushion, bed, car seat, and pressure relief habits.

Preliminary Results—Early results suggest that a majority of these subjects have cognitive deficits which may be attributable to closed head injury at the time of the SCI. Other psychological and nutritional information may be useful in predicting those patients at risk for repeated decubiti, indicating preventive intervention at an early stage.

Future Plans—The current award will terminate in September, 1990. In the interim, the evaluation aspect of the study will be carried out. Plans for work beyond September, 1990 are in development.

Development of a Microclimate Temperature Control Garment for People with Quadriplegia

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Purpose—People with high-level spinal cord injuries become poor thermoregulators due to inefficient sweating below the level of their injury. The problem results from a disruption of the communications pathways between the brain and sweat glands and blood vessels in the skin. The lack of adequate evaporative heat loss in high temperature surroundings or during exercise can cause a dangerous rise in body temperature with serious and sometimes life-threatening implications. The purpose of this study was to provide a definition of the need fo. body temperature regulation as expressed by people with quadriplegia, and to recommend to manufacturers of available personal cooling technology (such as cooling vests used by steel workers), the requirements for developing a microclimate temperature control garment for the target population.

Progress—A Phase Zero needs assessment study has been completed and a final report titled, "Microclimate Thermoregulation Garment for People with Quadriplegia—An Applications Engineering Prospectus," has been prepared. A functional design for an adaptive microclimate garment has been developed. The information used to develop this design included: 1) a review of the demographics of spinal cord injury; 2) a review of the literature on body temperature regulation and on personal cooling; 3) discussions with manufacturers of personal cooling products; 4) a survey of medical professionals who work with people with spinal cord injuries; 5) phone interviews with persons with quadriplegia; and, 6) a focus group discussion with potential users of a temperature control garment.

Results—The number of people with quadriplegia who experience thermal stress is estimated to be 25 percent of the total spinal cord injured population, or about 54,000 people in the United States, with between 1,800 and 1,900 potential new users each year. For these individuals, it is a significant problem that must be dealt with almost daily during the Spring and Summer. In addition, it is more important to prevent the thermal stress from occurring, rather than react once the symptoms become noticeable. The current coping strategies found most effective, aside from avoiding warm temperatures altogether, involve the direct application of water or wet clothing to the skin throughout the heat exposure.

The response to the concept of a microclimate temperature control system by potential users in a focus group discussion was highly favorable. Portability and light weight were emphasized as important requirements, as were avoiding high pressure on the skin, and ease in putting it on/taking it off. Safe temperature control was also a concern, especially since most people with quadriplegia cannot feel the cold on insensitive skin. The consensus was that a product to help alleviate thermal stress would have to be durable, reliable, and a good value in relation to its cost. Experience indicates that $200 would be reasonable for most individuals, $500 for some, but over $500 for very few people. Also, it would have to fit the individual and often active lifestyles of its users, and be easy to use and to maintain.

Future Plans—The use of existing technologies is likely the most effective way to develop a microclimate thermoregulation garment for people with quadriplegia. The prospectus prepared as a result of this research should serve as a set of guidelines for developing this new product. The final report will be distributed to rehabilitation professionals and to appropriate manufacturers of personal cooling systems, as well as marketers of rehabilitation products, to actively solicit industry in the development and evaluation of an adapted temperature control garment.

Effect of Exercise on Upper Extremity Recovery Following Quadriplegia

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Acute quadriplegia is commonly followed by some recovery of function in one to two spinal segments at the level of the cord injury. A patient with C4 quadriplegia often recovers some C5 function, allowing use of the upper extremities for operating an electric wheelchair or for self-feeding. This upper extremity recovery likely results from several recovery mechanisms including: 1) resolution of a transient conduction block in descending motor pathways of the spinal cord or in lower motoneurons or roots; 2) motor axon sprouting by spared motoneurons to reinnervate denervated muscle fibers; and, 3) muscle fiber hypertrophy in spared motor units.

This study will utilize a battery of electromechanical and electrophysiologic tests to describe the time-course of upper extremity recovery in acute quadriplegic subjects and to distinguish the mechanisms mediating this recovery. We will also electrically stimulate the nerve to a weak muscle in one extremity, and compare its recovery to that of a weak muscle in the opposite extremity. These studies will provide a better understanding of the recovery process in acute quadriplegia, and of the effectiveness of nerve electrical stimulation as a therapeutic intervention.

Publications Resulting from This Research

Electrodiagnosis and Recovery of Function. DeLisa JA, Little JW, *Am J Phys Med Rehabil* 67:44-49, 1988.

Measurement of Muscle Stiffness in Paraplegics

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Sponsor: *Scottish Home and Health Department*

Purpose—Since paraplegics suffer from spasticity, which includes muscle stiffness, it is important to be able to assess the effects of various treatments, such as drugs and muscle stimulation. Therefore, an objective method of measurement of stiffness has been developed.

Progress—Muscle stiffness is defined as the resistance of non-active muscle to passive stretch. Thigh muscle stiffness was measured in complete spinal cord injured (SCI) and non-injured subjects. Passive movement of the lower leg in the horizontal plane was induced by a torque motor, and the resulting displacement, known as Torque Induced Motion Analysis (TIMA), was recorded. Two complementary ways of measuring stiffness were used: 1) slow frequency (0.2 Hz) extension and flexion movements were used to calculate stiffness, i.e., torque divided by displacement (Nm/radian); and, 2) gradually increasing frequency (0.1–1.6 Hz) gave rise to a resonance, the frequency of which is also proportional to muscle stiffness. Muscle stiffness measured in this way was related to clinical estimates of stiffness, and was shown to be much more precise, and small differences could be shown to be statistically significant.

Measurements have been made on complete SCI patients to investigate thigh muscle stiffness changes with time of day, from day to day, with level of injury, time after injury, and size of leg. These data have been compared with that of non-injured volunteers. Muscle stiffness is different from one individual to another, whether paraplegic or not, and there is considerable overlap in the data between the two groups.

Preliminary Results—The effects of a short period of passive leg movement or electrical stimulation of thigh muscle on the subsequent immediate measurement of muscle stiffness were also followed. Preliminary results show that passive movement caused a significant decrease in thigh muscle stiffness in all cases measured, and supports the theory that physiotherapy can have a positive and measurable effect. Thigh muscle stiffness measured immediately after a period of quadriceps stimulation showed a small increase; but EMG activity, measured simultaneously, was absent, showing that stiffness is a true property of the muscle and is not due to nervous activity or muscle contraction. Some of the paraplegics were involved in a long-term quadriceps stimulation program. However, the trained muscles did not show any increased muscle stiffness compared to the untrained muscles. Therefore, the effects of muscle stimulation appear to be transient.

Longitudinal Assessment of the Utilization of Upper Extremity Assistive Devices Prescribed for the Spinal Cord Injured Quadriplegic Patient

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Purpose—The prescription of upper extremity assistive devices that facilitate physical functioning is a major component of the rehabilitation process. For the individual with a spinal cord injury and resultant quadriplegia, these devices mean the difference between dependence and independence, inactivity and productivity. While these devices are used on a daily basis during the hospital stay, they may be subsequently discarded once the individual has resumed his place within his family and the community. This study investigated upper extremity assistive device prescription practices, patient utilization, and satisfaction 1 and 2 years post-discharge from a comprehensive rehabilitation program.

Methodology—This study was a longitudinal prospective investigation employing an oral questionnaire as its primary tool. Fifty-six subjects with quadriplegia secondary to spinal cord injury were queried 1 and 2 years following their first rehabilitation experience. Data were analyzed using an analysis of variance with repeated measures.

Results—Of the 250 devices prescribed, 25 percent were feeding devices, 45 percent were splints and slings, 7 percent were dressing devices, 6 percent were hygiene and grooming devices, 11 percent were communication devices, and 6 percent were miscellaneous devices. A 4-way analysis of variance incorporating the major grouping factors of age, level of injury, and work/school status indicated that patterns of usage for all devices were similar regardless of the sub-populations studied. However, analysis of the repeated measure factor (mean level of device usage over 3 time periods) indicated a significant decrease over time ($p<0.001$).

A total of 54 percent of the devices prescribed during rehabilitation were in use at the end of one year, indicating a significant decline in device usage ($p<0.001$). There was a further significant decline in device utilization by the end of the second year, to 35 percent of all prescribed devices still in use ($p<0.008$).

Implications—Although the prevalence of quadriplegia is relatively low, the rehabilitation of these individuals is extremely costly. A portion of the costs is attributable to the array of assistive devices prescribed for these patients to enhance their performance of activities of daily living. Today, reimbursement for rehabilitation services and equipment is the major concern among health care providers. Third-party payers require evidence of the rehabilitation outcomes before they decide what funds they will allocate. For this reason, clinicians who provide the services and prescribe the equipment are becoming much more aware of how to document outcomes and obtain follow-up information in order to justify payment. The results of this study have heightened therapists' awareness of the efficacy, durability, and utility of upper extremity assistive devices. In some cases, the occupational therapists have developed alternatives to the traditional, commercially available, and frequently more expensive devices. These have included devices fabricated by the occupational therapists themselves and the identification of less expensive models of the equipment. In other cases, patients used the occupational therapy equipment from which they were weaned prior to discharge. By determining the long-term utilization and levels of satisfaction with these devices, the occupational therapist is able to eliminate the prescription of some devices, modify methods of patient instruction in the use of some devices, and develop alternative products. Both the consumer and the professional will find this financially beneficial. Although there may be incidents of device over-prescription, this does not appear to occur in the categories of the most expensive devices.

Development of a Wheelchair-Accessible Weight-Training Apparatus

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Sponsor: *Variety Village Sport Training and Fitness Centre*

Purpose—This study has the following objectives: 1) to design and fabricate a self-contained weight-training device which is versatile, accessible to, and adjustable by a paraplegic wheelchair athlete; and, 2) to assess the performance of the device at the Variety Village Sport Training and Fitness Centre.

Progress—Wheelchair athletes experience special problems using existing weight-training equipment at Variety Village. Awkward equipment adjustments, wheelchair inaccessibility, and lack of user independence often lead to frustration and discouragement.

The weight-training device developed for this project is multiadjustable and incorporates many of the functional features of commercial multistation gyms. However, this device has the added advantage that safe operation is possible while the user is seated in a wheelchair.

Results—The performance of the weight-training device was assessed at Variety Village with the assistance of eight wheelchair athletes who used the equipment regularly for at least one month. At the end of the field trials, each participant completed a questionnaire that recorded the frequency of use, range of adjustments, frequency of adjustments, and queried system performance.

Results of the questionnaires indicated that the device was well-received by all participants. All found it to be useful for its intended purpose.

Future Plans—This device is at Variety Village and is available for use by all its members. Patent proceedings have been initiated for the equipment designed.

Publications Resulting from This Research

Development of a Wheelchair Accessible Weight-Training Apparatus. Ryan S, Millage J, Gibbs C, Naumann S, *Proceedings of ICAART '88*, Montreal, 240-241, 1988.

V. Wheelchairs and Powered Vehicles

A. General

Linear Synchronous Motors for Power Wheelchairs

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B338-3RA)*

Purpose—The purpose of this research is to realize a more efficient power drive mechanism for wheelchairs.

Progress—Towards that end, we have built a curvilinear synchronous motor consisting of permanent magnets and stator pole windings built into the wheel, so that the field is primarily parallel to the wheel itself. By this means, standard drive couplings such as belts and chains are eliminated. Secondly, forces are generated at the outermost radius of the wheel that results in an optimum torque-producing geometry. The winding is 3-phase, and is controlled by Hall effect probes which sense the position of the rotor relative to the stator. Optimum use of the rare earth magnets is realized by making the motor 2-sided, i.e., having a stator on both sides of the rotor. The stringent requirements of weight for the chair necessitate the minimization of iron. The present design utilizes a one-eighth inch thick rotor and one-quarter inch thick stator. The choice of iron and depth of the stator slot is critical, since the motor is operating in saturation.

The present choice of control is a pulse-width modulation-switching thyristor circuit. The best efficiency is realized when the field voltage matches the back electromotive force (EMF) generated by the rotor generator action. We are presently examining alternative control scenarios which are more robust than the present design, but entail a lower trade-off in efficiency. Torque and efficiency measurements will begin upon completion of the machining of the 2-sided motor.

Publications Resulting from This Research

On the Design and Control of Low Speed Fractional Horsepower Synchronous Drive Motors. Davey K, Bass D, Ross D, Kelley G, in *Proceedings of the National Science Council* 11(5):398-410, 1987.

Design and Control of a Curvilinear Synchronous Wheelchair. Davey K, Bass D, Ross D, in *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:547-549, 1987.

Analysis and Control of Low Speed Fractional Horsepower Synchronous Drive Motors. Davey K, Vachtsevanos G, Bass D, Ross D, Kelley G, *IEEE Trans Indus Electron* 35(2):239-244, 1988.

Self-Operated Mobility Aids

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Sponsor: *VA Rehabilitation Research and Development Center Core Funds*

Purpose—Two mobility devices to assist paraplegics and quadriplegics have been built by graduate student design teams under VA Rehabilitation Research and Development Center sponsorship. They are being tested and evaluated with respect to existing alternatives under laboratory and actual use conditions.

Progress—The first device is a lever-operated wheelchair which has the potential to use the power of the human arm more efficiently than conventional wheelchairs. It has several gear ratios for use under different conditions (slopes, etc.), and the ability to select forward, neutral, or reverse gear.

A general test plan and a detailed subject questionnaire for the lever-driven wheelchair has been completed and has been given approval for human subjects testing. Early results show that lever-driven wheelchairs, in general, place greater loads on front casters than do conventional chairs. Details of the layout of courses to test hill-climbing, maneuverability, and capability on various terrains are currently being completed.

The second device is a self-operated lift to enable a quadriplegic, or other person with little or no upper body strength, to transfer between a bed, a wheelchair, and a bath without the assistance of an attendant. The device is similar to a forklift, but with multiple tines. These tines slide under a user by interacting with a multi-tube air mattress, and are connected to a beam that is hinged, so that it can be folded into a chair shape (an additional air mattress is necessary for a wheelchair).

This system, exclusive of the remote-controlled, motorized base which would eventually be necessary, has been built. A second mattress as well as covers for the tines are currently being made. A general test plan has been completed and approval for human subjects testing has been obtained.

Handbike: An Arm-Powered Bicycle

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Sponsors: *VA Rehabilitation Research and Development Service (Project #B807-EA); Telephone Pioneers of America, British Columbia Program for the International Year of the Disabled Person (University of British Columbia Athletic Department); Stanford Mechanical Engineering Design Division; Stanford Center for Design Research*

Purpose—The purpose of this study was to develop, evaluate, and make available an arm-powered bicycle for individuals with lower-limb disability that would provide many benefits including fitness, therapy, mobility, integrated recreation, and sport.

Progress—The development of the Handbike arm-powered bicycle is essentially complete. On the Handbike, the rider both powers and steers the front wheel through arm-cranks which essentially replace handlebars found on a standard bicycle. Back-pedaling actuates a caliper brake. The rider sits with his or her legs to either side of a crank tower, which may be folded onto the leg rest for easy transfer to and from a wheelchair. Side casters provide support at an adjustable bike lean angle (10, 15 or 20 degrees). The side casters may also be fastened down to create 4-wheel stability for going up ramps and indoors. Evaluation of the Handbike is continuing under the auspices of the VA Rehabilitation Research and Development Evaluation Unit. A company is forming with plans to begin production of the Handbike by January, 1989.

Results—With the evaluation underway, results should be available soon. However, initial results of test riding and evaluation have been very encouraging, and a few individuals have bought Handbikes through custom bicycle builders.

Future Plans—The current work focuses on technical support of the Handbike evaluation process, and the transfer of information to facilitate production.

Quantifying the Benefits and Costs Associated with Implementing International Wheelchair Standards

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The purpose of this study is to evaluate existing International Standards concerning wheelchair performance and determine the benefits to users, prescribers, and manufacturers, by adhering to these standards.

Progress—Records of running costs and reliability of 200 powered wheelchairs were analyzed to identify major trouble areas. A laboratory is being equipped to test wheelchairs against the draft International Standard for wheelchairs. Preliminary testing is already confirming that weak points in wheelchairs as shown in user records are being exposed in these tests, indicating: 1) the tests are representative of everyday usage; and, 2) if compliance with the Standard was obligatory, testing would have led to the designing out of some weak areas. Work still to be completed includes quantifying the additional costs to manufacturers incurred by testing, completion of the remainder of the laboratory to cater for the remaining parts of ISO 7176, and design and implementation of additional testing to be incorporated in the future Standards Association of Australia Standard. Input to the ISO 7176 has already been made as a result of findings from these tests.

Future Plans/Implications—With completion of the test laboratory, it is proposed to seek National Association of Testing Authorities (NATA) accreditation to enable tests to be carried out on an authoritative basis. A group of five wheelchairs meeting or exceeding the Standard's requirements will be subjected to a similar usage pattern as that of a group of five failing to meet the requirements. Complete records of running costs, repairs, and downtime will be kept. The cost of testing and design changes necessary to ensure compliance will also be recorded. The experience gained in the testing will enable us to contribute significantly to the proposed Standard. Future wheelchairs made to meet the requirements of the standards are expected to show increased reliability and economy, giving greater user satisfaction.

Costs and Benefits Associated with Limiting Deep Discharge of Wheelchair Batteries

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The purposes of this study are: 1) to verify that the premature curtailment of battery life is partly due to excursion into "deep discharge"; 2) to quantify the cost to the wheelchair user of this effect; 3) to investigate the efficacy of several revival techniques for batteries; and, 4) to design and build a discharge limiter addressing the problems of safety, deliberate abuse, and accuracy.

The design is to include versions for incorporation into new controllers and also a "retrofit" version to enable current wheelchairs to be so equipped.

Progress— Data already exists concerning the relationship between depth of discharge and battery life. Designs exist for deep discharge indication. Investigation into wheelchair user behavior indicates that a multistage approach should be explored. The first indication to the user would be that his batteries were approaching discharge. The second would be a marked alteration to the performance of the wheelchair. The final would be an actual cut-off of power.

Future Plans/Implications—A prototype limiter is to be developed and fitted to six wheelchairs. Battery performance before and after fitting will be recorded in detail along with user/caregiver comments. In Regency Park Centre alone, an increase in battery life to an average of nine months would represent a saving of $8,000 per annum. As it is intended that the deep discharge limiters should be applicable to all electric wheelchairs, there is potential for a reduction in running cost of up to 40 percent, with the additional saving of resources used in battery manufacture.

Battery Charger Comparative Evaluation

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The lifetime of gel-cell batteries being used at the Regency Park Centre for Young Disabled is significantly below that to be expected from the manufacturers' data. It is thought that one reason for this is incorrect charging. This research project aims to evaluate the performance of a range of battery chargers and to assess their cost effectiveness and suitability for charging gel-cell batteries.

Progress—A comprehensive Battery Charger Test Facility has been developed. This facility uses an IBM PC compatible computer connected to an HP3457A Digital Multimeter fitted with an HP44492A Reed Relay Multiplexer Assembly. This system is able to periodically measure battery voltage (DC, ripple and peak), current (DC and ripple), mains voltage and temperature for the entire duration of the charging sequence. The measurement sequence and data collected is controlled by software written in GW BASIC.

Future Plans/Implications—Battery chargers will be tested using the same set of batteries and subjected to mains input voltage near the maximum and minimum limits. Percentage overcharge, peak charge voltage, maximum case temperature, room temperature and power output after four minutes will be measured. The eleven different types of 24V battery chargers available in Australia will be subjected to the automated test and a comparative table of results generated.

Toward Further Development of a Modular Wheelchair Tray for the Severely Physically Disabled

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Sponsor: *National Health Research and Development Programme (Health and Welfare Canada)*

Purpose—To continue development of a modular wheelchair tray which meets the therapeutic goals of the therapist and the personal needs of the user and caregiver.

Progress—A 2-year research and development project, which ended in June of 1987, was undertaken to develop a wheelchair tray system which would meet the needs of severely physically disabled persons.

In December of 1987, Phase 2 of this project commenced. The goal of Phase 2 was to develop further the wheelchair tray system based on the results of the earlier study. The development of the second generation modular system focused on creating hygienic, lightweight tray modules that could be customized to accommodate the client and his/her seating insert, as well as the user's communication device and wheelchair control interface, when appropriate.

The first "module" created to meet these criteria was a basic flat tray. The tray was a laminate construction consisting of a tough, molded Kydex (acrylic-PVC alloy) surface and a stiff plastic core. To cushion the tray and protect any delicate communication device nested in the tray from inadvertent collisions, an integral lip reinforced with high-density polyethylene foam was provided. A precut polycarbonate cover protected graphic communication displays or other augmentative communication devices from moisture and foreign matter ingress. Molded armrest mounts with customized support spacers interfaced the basic tray system to the wheelchair and its user.

One tray mold was fabricated and a number of vacuum-formed trays have been produced for evaluation. An informal clinical assessment of the serviceability of this tray configuration was conducted.

Future Plans—The second module to be developed will incorporate a hinged, distal section. It is this section that will house any one of a number of typically-dispensed communication devices. This module will also provide the feature which will permit the tray to be stowed beside the wheelchair.

Following Design Review, both flat and foldable tray systems will be assessed through clinical trials. The project will be completed in early 1989.

Multiposition Size-Adjustable Wheelchair

L. Koet
Linido b.v., 2640 AB Pijnacker, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our purpose is to develop a wheelchair that is adjustable to all sizes (seat and back angle). It is also our goal that the user would adjust the wheelchair independent of any assistance.

Progress—At the moment a trial series of 12 wheelchairs is being developed.

This project is being conducted in cooperation with TNO Product Centre.

Kiss-Car

R. Potman
't Roessingh, 7522 AH Enschede, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our goal was the development of a simple, compact and affordable electric wheelchair (electric power, mechanical control).

Results—The project resulted in a satisfactory final product called the "Kiss-Car," which is now being mass-produced. A study is being conducted to determine to what degree this wheelchair will save time for a nursing staff.

This project was conducted in cooperation with Huka, Oldenzaal.

Wheelchair Lock in Subway "Roll Lock"

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TNO Product Centre, 2601 CX Delft, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our purpose was to develop an aid with which users of wheelchairs can quickly secure their wheelchairs in the Amsterdam subway. It would enable the wheelchair user to travel comfortably, without being annoyed by movements of the wheelchair caused by acceleration, braking, and lurching of the train.

Results—The developed aid is called "Roll Lock," and is now commercially available. "Roll Lock" can be used with most kinds of wheelchairs, but does not meet the demands for wheelchair security in cars which have been stated by the Ministry of Transport Industries in The Netherlands.

This project was conducted in cooperation with Rehabilitation Centre Muiderpoort (RCM), Dept. of Rehabilitation Technique, Amsterdam; Municipal Transport Firm, Amsterdam; and The Foundation for Consultation of the Disabled, Amsterdam (FCDA).

Hand-Propelled Children's Wheelchair

J.R. Veldink
Veldink Techniques, Stadskanaal, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The objective of this study is the improvement of the design and manageability of the wheelchairs known to date. A number of demands concerning function and weight are set, especially in connection with independent movement. One of these functional demands is high/low adjustment which would give the chair a drive and a work position.

The primary aim is the realization of qualitative improvements in the living conditions of young people with a physical handicap; the secondary aim is the increase of industrial and commercial activity within The Netherlands.

Progress—After several functional models were tested for six months in cooperation with the Communal Medical Service and a number of rehabilitation centers, a prototype will now be constructed.

This project is being done with the cooperation of Van Haaster and the University of Twente.

Development of a Multifunctional Electric Wheelchair

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Revab b.v., 7064 ZG Silvolde, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Definition of the problem: because of bad sitting/lying elements of wheelchairs, most people using them cannot sit up for more than a few hours. Thus, the time they can participate in any production process is considerably restricted. Also, the limited maneuverability and the limitations of the height adjustment of wheelchairs is restrictive for various jobs. Therefore, the purpose of this project is the development of a wheelchair that does not have the above-mentioned disadvantages, and is especially suitable for use under working conditions.

Progress—A concept has been defined for the wheelchair to be developed, with the following characteristics: 1) suitable for use in- and out-of-doors; 2) a high degree of modularity; 3) good springs and well-cushioned; 4) good adjustability for height; and, 5) the ability to move sideways.

Results—Development is progressing successfully, with only a slight delay. Some mechanical problems were discovered during the testing of the prototype, which we feel can be corrected.

This project is being carried out with the cooperation of Delft University of Technology, Department of Industrial Design, in collaboration with D. Smit; BIO Children's Rehabilitation, in collaboration with Het Dorp; and, Revab b.v., in collaboration with Ingenium b.v.

Lever-Powered Wheelchair

H.J.A. Stuyt
Revab b.v., 7064 ZG Silvolde, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this study is to develop a wheelchair that has been ergonomically improved with lever-powering for people who: 1) are unable to propel a hoop wheelchair (e.g., in the case of hemiplegia); and, 2) demand a large amount of mobility outdoors (wheelchairs with lever-powering are suitable for covering long distances at high speed).

Results—Following the description of the problem and the goal, an overview of the investigations and developments in the field of lever-powered wheelchairs was obtained in the course of a preliminary study. On the basis of this overview, it was possible to formulate a program of demands which should be met by the new lever-powering. Consequently, various solutions to the powering were taken into consideration. Out of these possibilities, a choice was made. The powering principle was worked up into a test model. With the test model, more information was obtained with regard to the various characteristics of the new powering mechanism.

This project was conducted in cooperation with the University of Twente.

Special, Individual Transport Provisions for Handicapped People (Motorized, Non-Electrically-Propelled Vehicles to be Used Outdoors)

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Development of a 40-km/hr vehicle for disabled people which, in comparison to current vehicles, is improved on the following points: comfort during driving (springs, seat size, and operation); accessibility of the vehicle; possible to take luggage along (including wheelchair); and design.

Progress—The project is in the final stages. A prototype is being constructed with which a final user research will be conducted. According to plan, activities were concluded in the Fall of 1988, with a full report due out by the end of the year.

Future Plans/Implications—The entire project will not be finished then. A follow-up investigation has been planned, for which financial aid has been obtained. Furthermore, the producer has made plans and investments in order to take the new vehicle into production.

Ergonomic Analysis of the Propulsion of Hand-Powered Wheelchairs

L.H.V. Van der Woude
Open University, Faculty for Kinetic Science, Department of Functional Anatomy; Erasmus University of Rotterdam, Faculty of Medicine, Department of Biomedical Science and Technology

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our objectives are threefold: 1) the formulation of demands for the standardization of the powering and sizing of the wheelchair and the interface between the wheelchair and the user, aimed at energy-economic transport, and the development of a protocol of guidelines for optimal positioning of the seat and powering on the basis of anthropometric data deducted from the individual and from patterns apparent from the investigation; 2) designing and developing a wheelchair simulator necessary for this goal, which includes specific possibilities for adjustment and measuring panels; and, 3) the deepening of functional-anatomical, biomechanical, and physiological theorization formulation concerning specific kinds of arm labor.

Progress—The wheelchair simulator was delivered in June 1988. Within the given limiting conditions, however, goals 1 and 3 have already been worked on. By means of experiments on the rolling pavement, knowledge has been obtained about the various factors which influence the use of energy, concerning both the technical aspects of the vehicle itself and the relationship between the vehicle and the user. Functional-anatomical and biomechanical parameters of the shoulder complex are being collected in a cadaver study that was started in September 1987, in collaboration with Delft Technical University. The relation between the dimensions of user and wheelchair are not yet explicit, because a standardized variation of the dimensions of the wheelchair is only possible on the ergometer. Attention will be focused mainly on this in 1988-1989.

This work has been carried out with the cooperation of divisions of the Delft University of Technology, Department of Measurement and Control Engineering and Cybernetic Ergonomics, and in collaboration with the companies Revab and Ingenium and the Mechanical Engineering Department of the University of Twente.

Mobility Aids for Handicapped Children

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our purpose was the development of a new generation of mobility aids for disabled children. The product will, in design, be tuned to the children's perception of reality and to industrial mass-production.

Progress—There are presently two designs for the so-called "BIOCAR," that enables small children to play at floor level. Start of mass-production is expected in the second half of 1988.

This project was developed in cooperation with Association Bio-Children's Rehabilitation Arnhem; and, Linido, Pijnacker.

Function Meter Car Control

A. Smulders
Smulders System b.v., 5628 BS Eindhoven, The Netherlands

Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is to develop a portable and easily-mounted kit for the determination of the ability of people with limited hand/arm function to drive a car. Through measurement, the kit should determine the following data: 1) steering couple or moment (maximally, and for long-term driving); 2) maximum and ergonomically-approved angular rotation, velocity, and acceleration; and, 3) tilt-couple or pressure-force exerted on the steering wheel in a car that is normal for the person, during a realistic driving test, in relation to the sitting position.

Ergonomics of Manual Wheelchair Propulsion

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Manual wheelchair propulsion is less efficient (8 percent) than other ways of human ambulation (e.g., cycling, 25 percent). The nature and causes of this apparent drawback have to be understood if optimalization is to be realized. The objective of the present research is to analyze the driver-wheelchair interface in search of kinesiological, biomechanical, and exercise-physiological aspects of wheelchair propulsion on a straight trajectory and on the dependence of driver, wheelchair, and interface-related variability.

Progress—Wheelchair types were tested on a motor driven treadmill: lever- and crank-propelled wheelchairs proved to be more efficient and less energy-costing than normal handrim-propelled wheelchairs. A special racing wheelchair appeared the least efficient (7.5 percent max). However, cardio-respiratory responses, frictional losses due to rolling drag, and air resistance were lower. Handrim diameter was of importance, the smaller rims leading to more efficient driving. Physiological response and movement technique in propulsion depended on power output (velocity, resistance) and on interface factors, such as seat height and shoulder position. Speed adaption in handrim wheelchair propulsion occurred primarily by adapting cycle-frequency, push-duration, and push-work. Duration of the recovery phase showed only a minor decrease, whereas the push range remained constant. Preliminary experiments and tests were done on a special-purpose wheelchair ergometer.

Results—Optimal cycle frequencies do exist and are not dependent on the level of power delivered. Rear wheel camber has stability, but has no effect on propulsive characteristics. Analysis of arm-shoulder movements was also developed.

Future Plans/Implications—The wheelchair ergometer was fully available in the Fall of 1988. Experiments will start on the biomechanics of the driving subjects under various, but exactly defined conditions of symmetric, asymmetric, constant or varying levels of loading. Force registration in three dimensions on the handrim, on seat and back rest, and movement registration will take place. At the load side, all losses can be simulated separately, as well as asymmetry simulating a transverse steep side walk or a turn.

The energy cost of activities in every day life of paraplegics will be measured. A preliminary study indicated that transfers were very costly.

Functionality and Durability of Manually-Propelled Wheelchairs

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1081 BT Amsterdam, The Netherlands

Sponsor: *Research Programme on Quality and Functionality of Aids for the Handicapped*

Purpose—The purpose of this study was to analyze individual complaints and appreciations regarding manually-propelled wheelchairs under daily use conditions related to impairment, intensity of daily use, and wheelchair brand and type.

Progress—Instruments developed for the whole sample were: 1) a telephone questionnaire (180 items) taken twice; 2) a failure-diary kept during the 9-month interval between interviews; and, 3) an activity-diary during a week in Spring, 1987. In 10 percent of the respondents, a technical examination of the wheelchair and an odometer mounted to the rear wheel of the wheelchair during a 9-month period, were administered in order to validate the instruments. Samples were drawn from populations of wheelchairs provided in 1982, 1983, and 1984 by the two major social welfare corporations in this country. Non-response amounted to up to 75 percent or more, resulting in a total sample of N = 609 respondents for the first telephone questionnaire.

Future Plans—Data analysis will be completed and a report on the main parts of the study and conclusions, as well as a critical appraisal of the methodology of this kind of research, will be published at the end of the year.

Research and Development Conducted to Improve Wheelchair and Seating Design (February 1988 to August 1988)

Clifford E. Brubaker, PhD; Colin A. McLaurin, ScD; John G. Thacker, PhD; James J. Kauzlarich, PhD; Rafael M. Inigo, PhD; James H. Aylor, PhD; Kao-Chi Chung, PhD
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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—In compliance with the mandate to carry out R & D activities to advance the state of technology in the priority areas of Improved Wheelchairs and Seating, 22 tasks were formulated to be conducted over the period from February 1, 1988 to January 31, 1993. A brief progress report is included for each active task during the current reporting period.

Survey and Technical Analysis of Wheelchair Deficiencies—(C. Brubaker and C. McLaurin): A comprehensive, nationwide survey has been undertaken to secure information from Independent Living Centers on the nature and frequency of wheelchair failures and other relevant data. The results will be compiled and used along with the results of testing undertaken at the UVA-REC. It is expected that this work will be completed and ready for dissemination by the end of October, 1988.

Wheelchair System Reliability Analysis—(J. Aylor): The overall objective of this effort is the application of state-of-the-art engineering techniques to the development of safe and highly-available electric wheelchair systems. Although 5 steps have been outlined in the development process, the ultimate goal is the development of a prototype of the next generation electric wheelchair. The new design will experience fewer repairs, less down-time, and safer operation.

The effort is broken into 5 phases: dependability (measured in terms of reliability, availability, and safety) analysis, frame and tire durability modeling, system study, bench prototype of system components, and powered wheelchair prototype. Results to date include a unique personal computer-based dependability analysis software system specifically developed for the analysis of wheelchair systems. Models of "mixed" systems, that is, systems containing both electronic and mechanical components, are possible. The user can be either well-versed in dependability analysis and develop novel models or have minimum expertise and develop system models from library-based elemental models. Failure rate dependencies influenced by factors such as aging and use patterns can be also modeled.

Tire Analysis—(J. Thacker and J. Kauzlarich): The performance characteristics of four 24-inch wheelchair tires are considered; one pneumatic and three airless. Specifically, two new airless polyurethane foam tires were compared to both a molded polyisoprene tire and a rubber pneumatic tire. Rolling resistance, coefficient of static friction, spring rate, tire roll-off, impact absorption, wear resistance and resistance to compression set were the characteristics considered for the basis of comparison. Although the pneumatic tire is preferred by many wheelchair users, the two new polyurethane foam tires were found to offer a performance similar to the high pressure pneumatic tires. In addition, the foam tires are less expensive and lighter in weight than the other tires tested.

Ride Quality—(J. Thacker and J. Kauzlarich): A systematic method of evaluating the ride comfort of wheelchairs is being developed. A review of the literature has been completed. Studies show that the clearest and most reproducible method for evaluating comfort is by using the ISO Standard *Guide to the Evaluation of Human Exposure to Whole-Body Vibration,* ISO 2631-1978E. Simple instrumentation has been specified utilizing piezoelectric accelerometers and a data acquisition system. Data is reduced using a fast Fourier transform routine to compute the RMS acceleration values in different frequency ranges specified by the ISO Standard. The test will be used to evaluate wheelchair suspension systems, wheelchair tires, and wheelchair seating systems.

DC-DC Converters—(R. Inigo): This project, initiated several years ago, used a commercial DC-DC converter. In addition, the control system was not truly adaptive, but only "adaptable." By using strain gauges to measure the user's weight, the extra necessary parameter to make the system adaptive (i.e., the inertia) can be measured for each different user automatically. The design of the DC-DC converter uses VLSI circuits, thus minimizing the number of components and improving reliability. Its efficiency is comparable to commercial converters.

Wheelchair Batteries—(J. Kauzlarich): A study of rubber dip coating methods for positive flat plate lead acid batteries has been started. This effort is to increase the charge/discharge cycles of a battery. Several rubber materials are currently being evaluated along with procedures for application including thickness and temperature.

Tissue Mechanics and Physiology for the Design of Seating Supports—(K. Chung, C. Brubaker, and C. McLaurin): The University of Virginia Rehabilitation Engineering Center is engaged in developing seat cushion systems which provide support, while optimizing pressure distribution. The emphasis currently is to measure the pressure at the buttock-cushion interface to determine the cushion shape. However, there is strong evidence to show that the tissue breakdown which leads to pressure sores begins at the pelvic bone and spreads toward the skin. Therefore, there is a strong interest in determining the stress distribution within the soft tissues of the buttocks. A viscoelastic finite element model of a human buttock segment is needed in the evaluation. Several analytical models for transferring loads through soft tissue have been proposed which all require numerical techniques. At present, the ischial tuberosity, the bottom part of the pelvic bone, is modeled as a rigid core with the rest of the tissue modeled as an elastic mass. Viscoelastic elements will replace the elastic elements once they are fully developed.

Optimization of Wheelchair Seating and Body Positioning—(K. Chung, C. Brubaker, and C. McLaurin): The custom contoured seat cushion has been successfully developed for spinal cord injury (SCI) and normal adults. Further clinical evaluation and mechanical testing have been conducted to determine the efficacy potential lifespan of the contoured cushion. Work has continued in the study of trunk support, the effect of body positioning on lower limb blood flow in SCI and, the effects of body support and positioning on muscle activities in Cerebral Palsy children. An analytic model of load bearing tissues has been developed that predicts the tissue deformation to correlate the results from MRI measurements.

CAD/CAM for Custom Seating Measurement and Body Positioning—(K. Chung, C. Brubaker, and C. McLaurin): A Kiethley Data Acquisition System has been used in conjunction with a personal computer to control a prototype 1 × 8 linear probe array. Several stepping motors have been evaluated with different drive screws resulting in a design specification. An initial contouring scheme has been programmed and is currently being tested. Electrical safety specifications have been determined. A computer aided manufacturing system which has the capability of cutting contoured cushions quickly and accurately has been developed. It has been used successfully in conjunction with a shape and pressure seat sensor developed at the Center. This system shows a cost-benefit potential to improve seating for both SCI and normal adults. A back contour sensing system has been designed to measure torso contour. Design of a pressure sensor based on the microbending of an optical fiber was completed.

Future Plans—Work on the remaining tasks will be initiated later during the current grant period and in subsequent periods as scheduled in our work plan.

Development of a Removable Wheelchair Brake for Sports Participation

Patricia E. Longmuir; Pawel Zbieranowski; Ronald Thompson; Peter Kostyan; Ihsan Al-Temen
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Sponsor: *Variety Club of Ontario—Tent 28*

Purpose—The rules governing participation in many wheelchair sports prohibit the braking mechanism from being on the wheelchair during play. This prevents injuries due to players getting fingers caught in the brake mechanism, and also reduces the possibility for applying the brakes as a strategy for defense. As a result, unless the athlete can afford to have a separate wheelchair exclusively for sports, the brake mechanisms must be removed prior to participation and replaced immediately afterward to ensure the athlete's safety during transport. Although many athletes are capable of performing this task on their own, those with limited hand function (e.g., quadriplegia, cerebral palsy) must rely on someone else. The need was apparent to develop a brake mechanism which could quickly and easily be detached from the wheelchair.

Progress—The initial prototype utilized a post which was permanently mounted on the wheelchair. The brake mechanism was attached to a hollow tube which could slide over the top of the post. The prototype was evaluated by a group of athletes. Support for the general concept was excellent, but concerns focused on the weight of the mechanism (particularly the section which was permanently mounted on the wheelchair), and the possibility for injury on the permanent post.

The subsequent prototypes utilized a clamping mechanism that did not require a permanently-mounted post. The entire brake can be removed with 3-5 turns of a knob. The brake will mount securely on many sports wheelchairs. Revisions to further reduce the weight of the brake (currently 320g) are underway.

B. Powered Controllers

Unistik® Vehicle Controller

Catherine W. Britell, MD
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Sponsor: *VA Rehabilitation Research and Development Service (Project #B218-DA)*

Purpose—The purpose of this project is to perform clinical evaluation of the Unistik® Vehicle Controller, a system of driving for severely disabled individuals, with emphasis on prediction of safety and efficacy of driving for subjects with various types of disability.

Preliminary Findings—Twenty-five subjects were enrolled in the study. Preliminary evaluation and testing has been completed on all those, and driving evaluation has been completed on 15 of the subjects. Seven are currently undergoing training and evaluation, and it was projected that the remaining subjects would complete driver training and evaluation by September 1, 1988.

The clinical evaluation consists of the following parts: *A. Psychological and Perceptual Testing:* 1) Mini-Mental Status Examination; 2) Tennessee Self-Concept Scale; 3) Multiple Affect Adjective Check List; 4) Symptom Check List 90-R; and, 5) Motor-Free/Visual Perception Test.

B. Motor Testing: 1) Manual Muscle Testing; 2) Functional Grasp and Release; 3) Nine Hole Peg Test; 4) Active Range of Motion; 5) Grip Strength; and, 6) Oppositional and Appositional Grip Strength.

C. Sensory Testing: 1) Sensory Level to Pinprick; 2) Joint Proprioception; 3) Stereognosis; and, 4) Visual Screening.

D. Driving-related Tests: 1) Written Rules of Road Test; 2) Wheelchair Driving Skill; and 3) Vision and Reaction Time.

E. Driving Range Skills: 1) Engine Startup; 2) Straight Line Tracking; 3) Turning (Right and Left); 4) Braking; 5) Serpentine Course; 6) Quick Stop; 7) Figure-Eight Maneuvers; 8) Straight Backing; 9) Backing Around a Curve; and, 10) Precision Close-Tolerance Driving.

F. City and Residential Driving: 1) Parking Lot Maneuvering; 2) Acceleration and Speed Maintenance; 3) Leaving Curb and Entering Traffic; 4) Braking; 5) Left Turn; 6) Right Turn; 7) Parking at Curb; 8) Backing from Driveway; 9) Parallel Parking; and, 10) Traffic Awareness and Judgment.

Following physical examination, psychological testing, motor and sensory measurements, and driving-related tests, each subject underwent training in the vehicle, starting on the driving range, and progressing to residential/city driving. Training time necessary to master driving skills with the device ranged from 6 hours to 32 hours behind the wheel, with an average of 12 hours. After training, driving ability was evaluated and scored, both with specific maneuvers on the driving range, and in city driving. Preliminary analysis of the test results indicate that measures of perception and psychological tests that indicate self-esteem and a self-concept that was "healthy" correlate with ability to drive. Muscle strength, range of motion, or sensation were not significant factors in the large majority of subjects.

The most universally successful driver interface or "handle" was a simple malleable U-shaped handle. However, many of the drivers required special modifications to the driver station, and a few required specially-adapted unique driver interfaces. This illustrates that with this system, as with many others in use, driving interface needs are very individualized and must be customized in nearly every instance.

Operation of secondary controls was evaluated. Since many subjects had very limited hand function and asymmetrical neurologic levels, it was anticipated that a large number of individuals would encounter a great deal of difficulty with operation of the secondary controls. In fact, the majority of drivers were able to use the secondary smaller joystick as designed especially for the Unistik® with ease.

Conclusions—The Unistik® system is a functional means of vehicle control for many disabled drivers who are unable to drive with existing vehicle control systems. Evidence suggests that each potential Unistik® driver will be best evaluated in a Unistik®-equipped training vehicle (van) incorporating a flexible driver station. Driver training by an experienced driver educator for the disabled with special training in this system will be essential for all potential drivers. Complete data analysis from the clinical evaluation is presently underway.

Ultrasonic Head-Controlled Wheelchair and Interface

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Sponsors: *VA Rehabilitation R&D Center Core Funds; Paralyzed Veterans of America; VA Evaluation Unit*

Purpose—The Ultrasonic Head Control Interface (UHCI) is a device designed to provide severely disabled individuals (quadriplegics) with a means of controlling devices, such as wheelchairs, in a socially acceptable and aesthetically pleasing manner.

Progress—In order to perform some tasks independently, severely disabled individuals must find communication pathways to replace the ones that have been totally lost, or amplify the ones that are impaired. High-level quadriplegics have a particularly difficult time in replacing lost or diminished channels to the outside world, since many of them can only control muscles at their neck level and above.

In this project, two Polaroid ultrasonic distance-ranging sensors are the basis for a new type of human-machine interface. They emit inaudible high-frequency sound waves which propagate through the air until reflected by an object. A portion of the signal incident on the object is reflected as an echo, and is detected by an electronic system. The elapsed time from transmission of the signal to the reception of its echo is proportional to the round-trip distance from the sensor to the object. Two separated sensors are directed at the user's head. The two resultant distance ranges, one from each sensor to the head, and the fixed distance between the stationary sensors, describe a triangle whose vertices are the two sensors and the user's current head position. A geometric relationship allows the offset from the base line and center line of the two sensors to be calculated. This information is then used to map the user's head position onto a two-dimensional control space. The array of distance-ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility, communication, and robotic devices.

In operation, the user of an UHCI merely tilts the head off the vertical axis in the forward/backward or left/right directions. The translation of head position information into electrical signals can mimic the output of a joystick. Both can be used to control devices to which they are attached, such as a wheelchair, a communication aid, a video game, or a robotic arm.

The main advantage of this interface is that no mechanical contact between the sensors and the user's head is required. This effectively separates the user from the device being controlled. The user does not feel confined as with devices in close proximity to the face or body, as frequently occurs with other interfaces. He/she would therefore not feel "wired-up" using it; an important factor in its acceptance. The use of the remote sensing ability of the UHCI should result in rehabilitation devices that are socially acceptable and cosmetically pleasing.

Results—UHCI have been installed on two electric wheelchairs. The first is an E&J model 3P equipped with a reclining Recaro seat, and is in use in France by a quadriplegic woman. The second is mounted on an Invacare Rolls IV with a Solo Products Power Pack and is being evaluated by spinal cord injury patients at this VA facility.

Both units have been operational since June, 1983. User evaluation has been performed with 10 quadriplegic individuals. After a short demonstration and training session, they were transferred into the chair and most were able to successfully navigate the chair without problem. Users stated that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs they had used. It is easy to use and does not result in user fatigue.

A generalized interface for a robotics application has also been developed. As with the UHCI, the robot user is able to select tasks and control the operation of a mobile robotic arm via head position. Specifically, the vehicle's navigation path is under the control of the user—its trajectory being "drawn" on a CRT with head motions.

A technical manual documenting the work on the UHCI, including background material, electronic schematics, computer program listings, explanations, and illustrations has been compiled. Its intended purpose is to provide information that would allow a technically knowledgeable and adequately equipped engineer to construct a duplicate UHCI and apply it to the control of devices such as powered wheelchairs. This manual has been made available to over 50 investigators considering the UHCI for research or commercialization.

Future Plans/Implications—Within the VA, a Request for Evaluation has been submitted to the Evaluation Unit and approved. The funds for the production of four commercial prototype units have been received. A solicitation has also been published and a manufacturer for those four devices has been selected from the responses. These devices will be evaluated at VA Medical Centers throughout the country. Finally, a decision will be made regarding the prescription of electric wheelchairs using the UHCI technology for appropriate severely disabled veterans.

A Study of Powered Wheelchair Controllers

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—This study has the following objectives: 1) to determine if new concepts in electronic wheelchair control are effective in improving the wheelchair driving performance of children with cerebral palsy, and to quantify any improvements; and, 2) to establish procedures for adjusting controllers to obtain optimum driving performance.

The outcome will be a protocol for establishing optimum controller settings in order to maximize benefits to users of electric wheelchairs.

Progress—This research is still in progress. A standard wheelchair joystick has been augmented to incorporate independent settings for maximum speed, acceleration, and damping. A digital wheelchair controller with velocity feedback from shaft encoders fitted to each motor will ensure that maximum speed and acceleration can be set to predetermined values.

Future Plans/Implications—Client trials began in October 1988. The results should clarify to what extent these new concepts in electronic wheelchair control are effective in improving wheelchair driving performance of children with cerebral palsy.

A Method of Simulating Wheelchair Controllability and Maneuverability in Confined Space

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Sponsor: *None Listed*

Purpose—The adjustment of wheelchair control parameters in conventional wheelchair controllers is generally limited to changing the maximum velocity of the wheelchair to one of two settings. Recently, electronic microprocessor-based controllers have become available. These controllers utilize digital signal processing which provides the opportunity to change a number of parameters which effect the controllability of wheelchairs. Such parameters include: maximum velocity, maximum acceleration, and "damping," which involves the filtering of the rate of acceleration (jerk).

The increased flexibility of digital controllers provides the opportunity to align the performance characteristics of a wheelchair, through the controller, to the wheelchair user's ability to control it. However, there is little information available which documents the effect of various parameter settings on wheelchair controllability.

Secondly, by interfacing a digital controller to a computer graphics-based wheelchair simulator, a valuable tool would be available to assist in the establishment of a control parameter regime for wheelchair users with specific disabilities. A further development of this simulation system would be to use it in conjunction with a computer-aided-design system to design and evaluate buildings with respect to wheelchair circulation.

Hence, the aims of this study are: 1) to establish a database which defines the performance characteristics of a wheelchair under different control parameter setting regimes when aligned to users with specific disabilities; and, 2) develop a computer graphics-based simulator which integrates the dynamic characteristics of a wheelchair, confined spaces found in buildings, and abilities of wheelchair users.

Progress—Currently, a data acquisition system is being developed to log controller output and wheelchair motion during a field study of wheelchair users. Data analysis software and wheelchair-modeling software is being developed. A protocol for the conduct of the field study is being developed. This trial will be undertaken in the second half of 1988 and the first half of 1989.

C. Seating Systems

Toward Further Development of a Seating System for the Physically Handicapped

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Purpose—This project has the following objectives: 1) to design and develop a versatile integrated seating system to meet the postural support needs of children with cerebral palsy; and, 2) to assess the performance of the prototype seating systems fabricated.

Progress—To enhance the service delivery of seating systems, an adjustable frame was designed upon which a variety of commercially available system components could be attached. The frame consisted of an arrangement of tubular steel designed to hold the seat and back components of the seating system. Initially, commercially available modular seat and back cushions were purchased and secured to the frame by independent vacuum-formed ABS pans. An adjustable headrest and polyester restraint straps for the trunk and pelvis were also secured to these pans.

Two types of frames were designed. The first type, intended for mildly involved children, was the "fixed" frame. The angle at which the entire frame was attached to the wheelchair was fixed at assembly. The second type of frame, intended for moderately-involved children, was the "tilting" frame. While fixed to the mobility base, the entire frame was adjustable to any angle from the upright position back to a 40-degree inclination. The angle between the seat and back was kept constant. Both frames had adjustable, telescoping tubes to allow for growth of the child. Also, both frames had flush bases to permit them to be positioned on a regular chair when removed from the mobility base.

Preliminary Results—Two of each type of system were dispensed as part of the study. Results of clinical and parental assessments indicated that the systems were generally well accepted. However, on the basis of other comments and the technical evaluation, further modifications are necessary before a dispensable, cost-effective system is made available.

Publications Resulting from This Research

Toward Development of an Integrated Seating System for Physically Disabled Children. Ryan SE, Martin M, Hill S, Scalabrelli L, Singleton D, Milner M, Lotto W, *Proceedings of the Third International Seating Symposium*, Memphis, 75-81, 1987.

Sitting Support That Can Be Individually Optimalized

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is to develop a sitting support suitable for use in a wheelchair that can be adjusted to the individual, and applied to various kinds of wheelchairs. The user should be able to control the sitting support him/herself. Attention is being paid to the following three aspects of sitting: 1) optimization of the sizes of the sitting support to the measurements of the user; 2) realization of a good sitting *posture*, tuned to the functional limitations of the user and the application of the wheelchair; and, 3) realization of a good sitting *position*, tuned to the application of the wheelchair.

Results—Our results are as follows: 1) The orientation phase has been concluded, resulting in business and market analyses recorded in a report. 2) The analysis phase has been concluded and a program of demands and relevant literature developed. 3) The designing phase has been concluded. As a result, ergonomic analysis, draft design, functioning principle, and a patent application for the tilting principle have been completed. 4) The materialization phase has been concluded. Constructive detailing of design, functioning model of the working principles, evaluation draft by means of evaluation model, and design study are finished. 5) Redesign is being prepared based experience gained from the model and the application of support in the electrical wheelchair.

Future Plans—The evaluation phase will be started after redesigning is finished.

This project was conducted in cooperation with Indes B.V., Oldenzaal; Delft University of Technology, Department of Industrial Design, Delft; Rehabilitation Centre 't Roessingh, Enschede.

Automated Measurement of Seating Interface Pressure

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Sponsor: *Rehabilitation Engineering Program, Department of Physical Medicine and Rehabilitation, University of Michigan*

Purpose—Pressure sores are a major problem for individuals who are wheelchair-dependent, particularly those with sensory losses. Many researchers have investigated the causes of these pressures sores and have sought methods of preventing them. Investigators in our program are currently studying the use of electrical muscle stimulation as a means of preventing pressure sores. This research requires the ability to dynamically measure and record the forces exerted at the seating interface. Additionally, measurement of pressure distribution is a useful clinical tool for evaluation of the seating interface.

Progress—A computer interface was developed to allow an IBM-PC compatible computer to acquire data from a commercially available pressure sensor pad. The pressure transducer for this device is the Texas Interface Pressure Evaluator (TIPE) pad. The University of Michigan interface, called the SPIRAL Pressure Monitor, has been used for both research and clinical seating evaluation. The TIPE pad is valuable for measuring relative seating pressure distributions and dynamic changes, but does not yield accurate absolute pressure readings.

The main problems with the SPIRAL Monitor stem from the technique of measuring pad air pressure to evaluate seating pressure. What is necessary is a thin, compliant, dimensionally-stable device which measures pressure directly. The need for this type of specialized transducer for characterizing the seating interface is well recognized (e.g., in July of 1988 the NASA Technology Applications Team published a problem statement to solicit assistance on this problem from NASA Centers around the country).

Future Plans—Our group is in the initial stages of investigating the applicability of a new measurement technology developed by the Department of Electrical Engineering at the University of Michigan. This technology is based on small, solid-state capacitive transducers. In coming months we plan to study whether it is possible to mount these sensors on a suitable substrate.

Publications Resulting from This Research

The SPIRAL Pressure Monitor. Jaros LA, Levine SP, Kett RL, Koester DJ, *Proceedings of the 1988 ICAART Conference*, Montreal, 308-310, 1988.

Custom Molding of Seating and Positioning Components Using the SPIRAL Pressure Monitor. Nelson RL, Kett RL, Levine SP, Koester DJ, Jaros LA, *Proceedings of the 1988 ICAART Conference*, Montreal, 310-311, 1988.

VI. Independent Living for the Disabled

A. General

Capuchin Monkeys as Aides for Quadriplegics

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B152-3D)*

Purpose—Research has demonstrated that capuchin monkeys can be successfully trained to serve as aides to mid- and high-level quadriplegics. During the last four years, efforts have focused on: 1) the standardization and refinement of the procedures by which monkeys are trained, equipped, and placed; and, 2) the development of resources that will allow for the actual implementation of the research results.

Progress—The following modifications were made to equipment and procedures during this past year: 1) Terminal locations on the shock/tone units were changed and wires were either eliminated or lengthened to reduce wear and tear as a function of monkey movement. 2) Modifications to the shock/tone harness were made which include the substitution of rubber electrodes for metal ones. These rubber electrodes are embedded in the tail strap, and, because they are rubber, can fit snugly against the skin without causing irritation. Proper fit has significantly increased the functional reliability of this unit. 3) A final design for the laser pointer has been generated, thereby setting the stage for production of the pointer by a commercial manufacturer. 4) Use of a "graduation" videotape has been initiated. This videotape shows a monkey performing its tasks in the lab, just prior to placement. On tape, a trainer explains step-by-step what mistakes that particular monkey is likely to make, and how to deal with the errors, should they occur.

Results—Resources which have been established to allow for a larger scale placement of monkey helpers are as follows: 1) The establishment of a breeding colony of capuchin monkeys at Disneyworld in Orlando, Florida, in April, 1988. This facility, built and maintained at Disney's expense, will contain 80 breeding monkeys. 2) The expansion of the foster care program. There are 70 monkeys now being raised and socialized in the homes of volunteer families across the country. This 3-year socialization period is a prerequisite for a monkey's entrance into the training program. 3) A videotape instructing foster parents in the basics of animal husbandry has been produced and distributed. The tape also includes instructions on how the foster parents can teach their monkeys to imitate, a skill that is very helpful in formal training.

Future Plans—This coming year will be a critical transition period as this project moves from a research to a service-providing orientation. It will also be a period of intense assessment as the VA Research and Development Evaluation Unit will be conducting an extensive clinical evaluation of 10 placements. Plans for this upcoming year include: 1) The placement of 10 monkeys with quadriplegics who are veterans. 2) The production of a videotape instructing local spinal cord injury professionals in how to conduct an at-home evaluation of a quadriplegic applicant. 3) The production of a videotape depicting the tasks that monkeys can be trained to perform. 4) The production of a videotape that depicts how monkey-related equipment is to be mounted on various models of electric wheelchairs. 5) The production of a placement manual that describes the proper care and maintenance of a monkey, as well as the most common problems that can arise, and how to deal with them.

Interconnection Standards for Electrical and Electronic Devices (InterSEED) for People with Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—A series of projects is underway to develop proposals for standardizing the connection between user interface devices and electrical and electronic assistive devices used by people with disabilities. These voluntary standards are developed in cooperation with manufacturers, clinicians, and users. Providing standardized connections between devices increased the ability for people with disabilities to select and use appropriate aid systems. In addition, standardization will make it easier for educators and clinicians to evaluate, prescribe, and apply equipment and software from various manufacturers.

Progress—Over the past year the Trace Center has been updating and revising existing documents to coincide with current technology and practice in the rehabilitation field. These documents include the Simple Electrical Transducer (SET) Standard and the Keyboard Emulating Interface (KEI) Standard. The SET document defines the connection, both physical and electrical, between user-operated controls (switches and rheostats) and communication aids and other such assistive devices. Today, virtually all major manufacturers of devices covered in this standard follow these specifications. The KEI document defines an information transfer protocol and connection for using an alternate keyboard device (e.g., communication aid) in place of the normal keyboard to operate standard, general purpose computers. This standard has been implemented in devices and programs for many popular computers and are available from several manufacturers.

In addition to these, a new area of focus has resulted in a standardized interface between electronic user-control devices and powered wheelchairs. This proposal would enable some control aids to be used to operate similarly intelligent powered wheelchairs. Progress continues on this proposal in cooperation with major wheelchair and assistive devices manufacturers.

Future Plans—A General Input Device Emulating Interface Standard will be developed. This standard, a superset of the KEI, will define a protocol for emulating devices such as a mouse, touch pad, additional keyboards, etc. Plans for testing various proposals with users have been made with actual testing to begin soon.

Publications Resulting from This Research

Keyboard Emulating Interface (KEI) Standard Proposal. (Revision 5.0). Schauer J, Kelso DP, Vanderheiden GC, Lee CC, University of Wisconsin-Madison: Trace Center, 1988.

Simple Electrical Transducer (SET) Standard Proposal (Revision 1.0). Schauer J, Kelso DP, Vanderheiden GC, University of Wisconsin-Madison: Trace Center, 1988.

Serial Interface Standard for Wheelchair Control Proposal (Revision 1.0). Schauer J, Kelso DP, Vanderheiden GC, University of Wisconsin-Madison: Trace Center, 1988.

Instrumental Social Support as a Buffer of Psychological Stress for Persons with Physical Disability

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Sponsor: *The Institute for Research and Rehabilitation*

Purpose—A primary purpose of this investigation is to understand some of the principal determinants of psychological stress in persons with physical disability. Accentuating this interest are two studies suggesting that persons with physical disability are at increased risk for psychological stress and diminished psychological well-being (Cohen & Williamson, 1988; Williams, Ware, & Donald, 1981). The proposed study is designed to test the hypothesis that the instrumental social support available to physically disabled persons is a key factor in determining the degree to which they experience stress and psychological dysphoria.

The research model underlying this project is based on the well-documented finding that social support can buffer the effects of stressors and result in less experienced stress than otherwise would be the case. According to the analysis of Schaeffer, Coyne, & Lazarus (1981), social support may take the form of emotional support (e.g., direct assistance with tasks). For persons in the general population, most studies have found that emotional or cognitive support is more important than instrumental support in buffering stress resulting from life events such as divorce, loss of one's job, or the death of a loved one.

Underlying the proposed study is the conception that physical disability entails distinctive stressors that are capable of producing considerable psychological stress unless buffered by instrumental social support. Those stressors involve the task demands of daily living, e.g., dressing, personal hygiene, preparing meals, shopping, and mobility throughout the community—operating in the face of chronic physical impairments associated with conditions such as spinal cord injury, muscular dystrophy, polio, multiple sclerosis, cerebral palsy, or arthritis. The assistance that persons with these disabling conditions receive in dealing with daily life activities comprises an important form of instrumental social support for them.

That support may vary considerably in its availability or, perhaps more importantly, its satisfactoriness as appraised by the disabled individual. Stress is the predictable result of needed assistance that is appraised as being insufficient or of unsatisfactory quality.

Operational Definition of Independence

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Sponsor: *The Institute for Rehabilitation and Research*

Purpose—This project is designed to develop an operational definition of independence that incorporates three dimensions of the term: perceptions of control over one's life, psychological factors, and behavioral or functional characteristics. The objective is to develop an assessment instrument to quantify an individual's independence in each of the above specified domains.

Progress—With appropriate expert consultation, a refined conceptual definition of independence has been generated covering each of the three dimensions of the term. An instrument called the Personal Independence Profile (PIP) was constructed to operationalize this definition, using items selected from Flanagan's quality of life domains (1978) rated on a 5-point Likert-type scale for perceptions of control and importance in one's life, items concerning feelings from Fordyce's Independence Scale (1954), measuring such psychological factors as competitiveness, self-esteem, group autonomy, etc.; and The Arthritis Impact Measurement Scale (AIMS) of Meenan, Gertman, and Mason (1980), a Guttman-type ordering of general functional ability items.

The PIP was first tested on 61 severely physically disabled subjects referred by an urban and a rural independent living center. A demographic questionnaire was also administered, covering basic personal characteristics, activity patterns, use of attendant services, and health. Analysis of data from the PIP using Cronbach's alpha supported elimination of dependence-oriented items from the Fordyce Scale, resulted in internal consistency ratings of the first two sections ranging from 0.71 to 0.89. The reliability of the third section, the AIMS, was tested using the coefficient of reproducibility resulting in scores of 0.87 to 0.93. A scoring mechanism has been developed yielding single scores for control and psychologic independence. This data set is currently being analyzed for correlational relationships between PIP scores and personal demographic and behavioral characteristics.

Future Plans—The next step in the development of the PIP will be to conduct various tests of its validity. Discriminant validity is currently being assessed by administering the PIP to 48 individuals of known characteristics referred by four independent living centers in various parts of the country. Congruence between their profile of scores and general assessments of independence given by independent living center staff will be determined.

Independent Living in Rural Areas: A Longitudinal Study

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Under a 3-year grant from NIDRR, the Independent Living Research Utilization (ILRU) expanded independent living opportunities for disabled residents of rural areas. Six demonstration sites were established and given ongoing support until the project was completed in April, 1986. The current Research and Training Center project is designed to examine the long-term effects of these interventions in terms of quality and quantity of ongoing activities and outcomes for the community.

Progress—The first component of this evaluation project has involved an initial assessment of two demonstration sites at the time that the ILRU rural demonstration grant was completed. This initial assessment allowed for the collection of baseline data to be used for comparison purposes following assessments in subsequent years. Two follow-up examinations of these demonstration sites will be conducted at 18-month and 36-month intervals.

Content and format for personal interviews of individuals with disabilities, service providers, clergy, and representatives of the media at each demonstration site have been developed. This protocol was pilot-tested on a sample of 10 individuals at one site, refined appropriately, and administered at the other two sites. All data gathered through the Community Needs and Resource Survey and individual interviews have been analyzed. An article presenting the results is in preparation.

The Definition of "Peer": Consumer Perspectives and Significance in the Delivery of Counseling Service

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Sponsor: *The Institute for Rehabilitation and Research*

Purpose—This project is intended to provide initial data on the perceptions of disabled persons with respect to the definition of "peer" and the provision of counseling services by peers. In this initial investigative effort, the research will be delimited to mobility-impaired persons. After the methodology has been developed and validated, additional research might focus on other disability groups. The methodology for the project will involve the development and pilot-testing of the content and format for the study; training of interviewers who will collect the data; collection of data from disabled individuals in various geographical locales to obtain a sample that is diverse with respect to age, ethnic mix, type of disability, and socioeconomic status; analysis of data collected from disabled consumers; and articulation and dissemination of research findings.

Progress—Analysis of the literature search and further probing of the Berkeley Planning Associates data from the national evaluation study, has yielded several persistent questions related to peer counseling. Most available information concerns outcomes from peer counseling services and debates over appropriate techniques for the delivery of these services. A question that never seems to have been asked is how the consumer perceives the services. Specifically: How does the consumer rate the credibility of the counselor? A design for this study has been developed which examines the degree to which these perceptions are influenced by whether or not the counselor has a disability, the content of the interaction (disability-related or not), and reputational cues given for the counselor (high or low). The dependent variable, consumer perceptions of counselor credibility, will be measured by items drawn from the Counselor Effectiveness Rating Scale of Barak and LaCross (1975). To reduce the length of this scale, only the 4 items which loaded highest on each of 3 factors were chosen. Format includes a Likert-type response. A brief demographic questionnaire, abbreviated from that used in R-1, will be administered to all subjects after testing.

Materials for the implementation of this design, including photographs of counselors and taped descriptions of counselor background and content of interaction have been prepared. Testing is underway at this writing. Full testing, coding and entering of data, and multivariate data analysis will occur before the end of this project year.

B. Robotics

A Natural-Language Interface to a Rehabilitative Robot: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Proposal #B942-PA)*

Purpose—When people and robots interact, some common language has to be found to allow them to talk to each other. That was the problem addressed by this project. Over the past several years, a general-purpose robotic device, the Robotic Aid, has been under development as an aid for people with severe physical disabilities. It consists of a manipulator equipped with a simple gripper and mounted on an omnidirectional vehicle. If this device is to be truly useful to disabled people, the problem of communication must be solved.

Three main points describe the problem: 1) Disabled users of a rehabilitative robot should not be required to learn a complex robot programming language. 2) Even if specially-trained technical personnel were readily available to program the Robotic Aid, the result would be a device that could perform only a fixed set of predefined tasks. 3) Intermediate languages have been designed in an attempt to bridge the gap between human and robot, but they have proved frustrating to the user, and of limited utility for controlling a device like the Robotic Aid that has to operate in a complex and changing environment. What is needed is a robot that can understand an ordinary human language such as English. The purpose of this project was to develop and demonstrate some natural-language understanding capabilities in the Robotic Aid.

Results—We identified an environment that a user of the Robotic Aid would frequently encounter: a workspace consisting of a table and bookcase scattered with books of various sizes and shapes. We also identified a range of tasks the user might want to perform in this environment, such as retrieving a book from a shelf and placing it somewhere on the table, returning a book to a shelf, rearranging books on the table or in the shelves, sorting books into piles or rows, and so on. We developed a system that understands and obeys a variety of ordinary English commands in this environment. Examples are: "Move the big book by Durrell to the top shelf"; "Get the thin book"; "Put it on the other side of the pile."

There are four major components to the system: 1) A set of basic robot actions. 2) A database subsystem that records the location and orientation of all objects in the environment. 3) An interpretive grammar that translates English sentences into representations that the robot can understand. 4) A program called the Dialog Manager that accepts user commands and lets the user know what the robot's response is to each command.

Future Plans/Implications—The prototype system we developed may now be demonstrated to potential users of the Robotic Aid for their response and evaluation. This will help ensure that the long-term development of the Robotic Aid takes into account the communication needs of people, rather than machines. Important progress has been made in identifying critical areas of natural-language communication for future work on the Robotic Aid. The three most important are: 1) Stop commands—the user must at all times be able to bring the robot to a safe and speedy halt. 2) Corrective commands—the user must be allowed to modify the action the robot has taken in response to an earlier command. 3) Teaching commands—the user should be able to tell the robot to remember instructions it has received for later use.

Publication Resulting from This Research

Using English to Instruct a Robotic Aid: An Experiment in an Office-Like Environment. Crangle C, Liang L, Suppes P, Barlow M, *Proceedings of the International Conference of the Association for the Advancement of Rehabilitation Technology (ICAART)*, Montreal, 466-467, 1988.

Clinical Evaluation of a Desktop Robotic Aid for Severely Physically Disabled Individuals

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B239-RA)*

Purpose—The purpose of this project is to study the use of robotic aids by severely disabled individuals and to demonstrate the reliability and performance quality of a third-generation robotic system in preparation for placement in home and vocational settings.

Progress—This study is part of a continuing research project to clinically evaluate the use of the DeVAR system . The robotic aid being evaluated is a Unimation PUMA-260 industrial arm controlled by an IBM-PC/AT computer, and operated by user commands through a VOTAN voice recognition unit. Prior robotic workstations used a standing, rotating kiosk to house supplies needed for activities of daily living (ADL) (toothbrush, shaver, utensils, etc.). Based on feedback from users on the space utilization, aesthetics, and time needed to access the supplies from the kiosk, a new workstation was developed for faster, more efficient task performance.

Improvements to the third-generation system, including improved voice recognition, more efficient, streamlined performance of tasks, improved aesthetics, and addition of new tasks, have been implemented and continue to be upgraded based on user feedback obtained through clinical evaluation. An educational video and a tutorial on the DeVAR system have been made and are used in training prospective users. To date, 20 high-level quadriplegics (neurological levels C3, C4, C5) with little to no use of their arms or hands have participated in the study to clinically evaluate the workstation. Disabled users were given questionnaires before using the workstation, followed by trial usage of the system to perform the following pre-programmed tasks through voice commands: 1) prepare meals (microwave, refrigerator); 2) feed with utensils (using spoon and fork); 3) brush teeth with electric brush and rinse; 4) wash and dry the face; 5) shave the face with electric shaver; 6) get a drink with a straw; 7) give user a mouthstick for typing; and, 8) operate ECU (phone, lamp, radio).

Results—Task performance was measured by task completion time, subjective user satisfaction, and objective measurement of task completion (reliability, thoroughness, outcome, etc.). Results of these posttest evaluations have been positive in affirming the robotic workstation's quality of performance. A large number of positive results were obtained for the sturdiness, safety, ease of use, obedience, value, and reliability of the system. Negative responses included immobility and personality of the system. When asked: "Given what you know about a robotic aid, would you want one in your home?," 15 answered "Maybe," and 3 answered "No" on the pretest. On the posttest, 17 answered "Yes" and 3 answered "Maybe": no one said they would not want one at home.

Future Plans—A fourth-generation workstation, emphasizing the combination of vocational and daily living activities, has been designed and taken into community vocational settings to be evaluated outside the clinical setting. Continued evaluation of the DeVAR system by the disabled user and medical and rehabilitation engineering professionals in multiple home and vocational settings is critical in creating a robust, reliable, robotic workstation for the severely physically disabled.

Publications Resulting from This Research

Evaluation of a Table Top Robotic Aid for Quadriplegics. Hall K, Glass K, Hammel J, Leifer L, Perkash I, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:776-777, 1987.

Clinical Evaluation of a Desktop Robotic Aid for Severely Physically Disabled Individuals. Hammel J, Hall K, Van der Loos M, Leifer L, Perkash I, *Proceedings of ICAART '88 Conference*, Montreal, 448-449, 1988.

Design of a Second Generation Desktop Robotic Aid. Lee D, Crigler B, Van der Loos M, Leifer L, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:796-798, 1987.

A Third Generation Desktop Robotic Assistant for the Severely Physically Disabled. Lees D, Crigler B, Van der Loos M, Leifer L, *Proceedings of ICAART '88 Conference*, Montreal, 450-451, 1988.

Development of an Omnidirectional Mobile Vocational Assistant Robot for the Severely Disabled

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Sponsor: *VA Rehabilitation Research and Development Center, VA Medical Center, Palo Alto, CA*

Purpose—Over the past two years, we have developed a laboratory prototype of the mobile vocational assistant robot (MoVar). Our current goal is to deliver a re-engineered, robust version of the robot, suitable for extended evaluation in clinical, home, and vocational environments, away from expert engineering support.

MoVar has two major components: a mobile robot and a stationary operator console. The robot consists of a PUMA-260 robotic arm mounted on a 3-wheeled omnidirectional vehicle. The robot is approximately the size of an electric wheelchair. It is able to turn in any direction while moving forward, backward, left or right. It accepts spoken commands, including commands that refer to movements of the vehicle. Because of the 3-degrees-of-freedom of the vehicle, a dedicated color display assists the user in keeping track of the location and state of motion of the robot with respect to a 2-dimensional map of the surrounding area. A third screen shows a black-and-white video image from a small camera that is mounted on the robotic arm. Selected functions of the robot can be controlled by motions of the user's head, which are monitored by a pair of ultrasonic range sensors.

Progress—In accordance with our goal of delivering a safe and robust pre-production version of the robot, the following activities have been completed or are in an advanced stage of implementation: 1) A segmented touch-sensitive bumper is mounted on the side of the vehicle. Software routines respond to bumper contacts by steering the robot away from the point where contact occurred. 2) A low-power laser scanner detects the presence of reflectors that are placed in the environment, allowing the robot to compute an accurate position and orientation. 3) Photoelectric proximity sensors have been installed in the robotic hand. A variety of voice-activated routines are available to detect the presence of nearby objects, to avoid collisions, or to grasp small objects automatically. 4) The robot's onboard computer is being upgraded from a DEC LSI11/73 to an Intel 80386, resulting in a 5-fold increase in computing power, with a decrease in system cost. The control software has been translated from Pascal into C, allowing for the use of a UNIX-based Operating System, and less expensive peripherals. Many enhancements have been added to the control software. Various electromechanical components of the robot are being upgraded: wheels, motors, power amplifiers, servo controllers, batteries, and voltage converters. 5) The operator console has been completely rebuilt. It has been mounted on casters and is fully adjustable for various wheelchair configurations. The new console provides improved sightlines for monitoring the activities of the robot. It includes storage space and a working area for vocational and daily living activities.

Publication Resulting from This Research

Development of an Omnidirectional Mobile Vocational Assistant Robot. Van der Loos HFM, Michalowski SJ, Leifer LJ, *Proceedings of the International Conference of the Association for the Advancement of Rehabilitation Technology (ICAART)*, Montreal, 468-469, 1988.

Evaluation of the Johns Hopkins University/Applied Physics Lab (JHU/APL) Robotic Arm for Spinal Cord Injured Veterans

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B041-RA)*

Purpose—The purpose of this project is to evaluate, by clinical trial, the utility of the Johns Hopkins University/Applied Physics Lab (JHU/APL) Robotic Arm/Worktable system in providing assistance to persons with high-level quadriplegia. When it becomes available, the first commercial robotic system will be evaluated and compared to the current prototype arm.

Progress—Utilizing spinal cord injured (SCI) patient volunteers, evaluation of the complete Robotic Arm/Worktable System is being conducted to determine the feasibility of this device. Concurrently, data collected from clinical studies is being utilized to design and implement modifications of individual Robotic Arm components to optimize operating effectiveness and minimize final cost. Using patient input, a series of defined tasks were designed for every subject. The veteran was then given a training period to master each task, and standard evaluation procedures were carried out to assess the patient's performance of this task. Detailed notes of each patient's participation, time to carry out various activities, and veteran's subjective comments were recorded. Following a defined protocol, subjects were assessed in each phase of operation of the Robotic Arm.

Results—Previous reports summarize the results of the project up to this year. As a result of that research, the Robotic Arm has gone through several design modifications. This year the current prototype arm/worktable has undergone numerous changes. The elbow cable was repositioned to increase the lift capacity of the elbow from one to three pounds, while decreasing the cable load. A rear stop was added at each wheelchair docking station; this simplified the docking system (the infrared docking unit is thereby eliminated), and reduces the cost of production. The telephone system now utilizes an inexpensive, commercially available headset phone. A large capacity liquid reservoir has been installed at the feeding station, also utilizing inexpensive, commercially available components. The X-10 Powerhouse, a low-cost environmental control system, has been added as a Macintosh peripheral.

Robot Arm/Work Station System for High Spinal Cord Injured Persons

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Sponsor: *VA Rehabilitation Research and Development Service*

Purpose—The goal of this continuing research is to complete the basic development of a working engineering model of the Robot Arm/Work Station to permit manufacturing a limited number of units at low cost, so that they may be placed in selected VA Spinal Cord Injury Centers.

One engineering unit was placed at the VA Medical Center in Richmond, VA, in 1986, to allow engineering modifications to be evaluated by selected volunteer quadriplegic patients under the direction of the therapist. This unit has been in continuous clinical evaluation since that time.

The Robot Arm/Work Station has been designed as a relatively low-cost system with safety of equipment and ease of learning and usage as the most important factors for system consideration. Most of the testing to date has been conducted using a wheelchair or table-mounted chin controller as the primary input device. At the request of the VA, some initial work has been carried out for using the VA Palo Alto-developed voice front end system as the primary controller for this work station.

The role of The Applied Physics Laboratory (APL) during the past year continues to be one of fine-tuning the engineering details of the system, assisting the VA in preparing specifications for a commercial unit, and to perform a transition of usage for the VA Palo Alto voice input front end to the APL work station.

Progress—The original Robot Arm/Work Station utilized the dual purpose chin controller mounted on a wheelchair. Due to lack of standardization of wheelchair usage by high-level quadriplegics, later work stations employed a chin controller mounted on the work station as the primary controller. This concept has been evaluated in clinical trials at the VA Spinal Cord Injury Center in Richmond, VA and proved to be highly workable. The importance of evaluation of engineering prototype in realistic clinical or user settings cannot be overemphasized. As tests are being conducted, any deficiencies and necessity for improvements are conveyed to APL, and modifications are made for continued system evaluation. Some of this year's changes to the work station system at the VA Medical Center in Richmond, included an improved telephone setup using a commercially available low cost telephone and an improved self-feeding arrangement. A new plate and mounting arrangement improves the ability to eat from a plate.

An important component on the work station at VA Richmond is the Macintosh Plus Computer. This advanced personal computer may be controlled by the quadriplegic using a specially-designed sip/puff transducer, including a "mouse" equivalent interface. This system has been evaluated and results are considered highly successful.

A preliminary study was made of a ceiling-mounted track suspending the robot to allow more flexibility in work station layout. The APL robot arm appears to be adaptable to this concept with moderate mechanical and wiring changes. Funding did not permit examining the concept beyond the preliminary layout stage.

At the request of the Veterans Administration, APL has been investigating the integration of the VA Palo Alto front-end voice system to the APL Robot Arm/Work Station. This change required the modification of the 6809 computer controller card to accept RS-232 input. This change has been accomplished and a new controller designed and evaluated to allow the unit to receive external inputs or the chin controller inputs. Some preliminary effort was jointly performed by VA Palo Alto and APL/JHU to demonstrate a compatible interface. This demonstration was highly successful. The changes to the computer card included the replacement of a customized, expensive display terminal and a separate custom keyboard with a commercially available hand-held terminal by Oyster, Inc. The changes to the resident software are virtually complete and checked out and the APL unit is ready for interface of the voice input interface.

Gripper Automation and Voice Control of Rehabilitation Robots

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Sponsor: *The Frost Foundation, Ltd.*

Purpose—The goal of this project was to enhance the usefulness of commercially available robots for rehabilitation applications.

Progress—Evaluation of several personal and industrial robots resulted in the selection of the RTX robot manufactured by Universal Machine Intelligence Limited for further development. Selection criteria included lifting capacity, range of motion, number of degrees of freedom, grip strength, and ease of programming. A kit is also available to mobilize the RTX. Evaluation of a number of speech recognition packages resulted in the use of the IBM Voice Command Adapter for voice control because of its vocabulary capacity, speed, and relative ease of use. Control of the robot was through high-level commands written in the C language to utilize low-level robot functions. Modules were also written in C to gather information from gripper sensors and to implement a gripper algorithm. The control computer was a Compaq Portable III with an 80286 microprocessor.

Automation of gripper function was undertaken as the most cost-effective enhancement to the robot. Eight LED-phototransistor pairs were housed in the gripper pads. Six pairs were used to obtain information on presence of and position of objects to be grasped. Two additional pairs were used for obstacle avoidance. An algorithm was developed to obtain sensor information in a scanning mode, decide the next arm or gripper action, and control robot motions. The resulting automatic gripping routine positioned the gripper around the object and caused the object to be grasped.

Robot control was also implemented in a voice-control mode of the robot. Phonetically dissimilar phrases were developed for the high-level commands. Complete control of the robot, including the gripper algorithm, was available in the voice-control mode.

Results—Automatic grasping was accomplished for a wide range of objects commonly encountered in activities of daily living and office work. Use of the voice-control mode with the gripper algorithm resulted in fewer commands and fewer errors for a given grasping task than occurred with control through the computer keyboard or through voice-control alone. In addition, groundwork was laid for objective evaluation and testing of robots for rehabilitation applications.

Future Plans/Implications—As robots become more available, less expensive, and more capable, their potential for rehabilitation application increases. Additional grasping capability and voice control of robots will further enhance robot usefulness in assisting persons with disabilities in daily living and vocational activities.

Wheelchair-Borne Manipulator (MANUS Project)

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our purpose is the product development of an economically acceptable, wheelchair-borne manipulator with individually adjustable, computer-supported control for people with serious function limitations of both the lower and upper limbs.

Progress/Results—Product development within the MANUS project is conducted in close cooperation with IRR, TPC-TNO and the TNO Product Centre. The first phase of the project contained the formulation of the functional concept, design, construction, and technical evaluation of a functioning model. The research and the development belonging to this phase were concluded in May 1987.

On the basis of evaluation of the trail model, a new design was made for a pre-production model of the system. The further development of the mechanization has been concluded: the electronics, basic software and three pre-production models will be completely shortly.

Future Plans—After conclusion of the product development, follow-up projects will be used for further development of the adjustments for various groups of users and for the evaluation and commercialization of the system.

Publications Resulting from This Research

Development of the MANUS Wheelchair-Borne Manipulator: A Progress Report. Kwee HH, Duimel JJ, van Woerden JA, Smits JJ, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:781-783, 1987.

Le Projet MANUS: Conception d'un Prototype de Telethese Porte sur Fauteuil Electrique. Kwee HH, Duimel JJ, van Woerden JA, Smits JJ, *Handitec 87*, Paris, 1987.

The MANUS Project: Development of a Computer-Assisted Wheelchair-Mounted Manipulator. Kwee HH, Duimel JJ, Smits JJ, Tuinhof de Moed AA, van Woerden JA, (Abstract) *North Sea Conference, Biomedical Engineering: Advances in Rehabilitation Technology*, Maastricht, The Netherlands, 1988.

MANUS: A Wheelchair-Mounted Manipulator (Abstract). Kwee HH, Duimel JJ, Smits JJ, Tuinhof de Moed AA, van Woerden JA, v.d. Kolk LW, *Cardio-Stim 88*, Monaco, 1988.

The MANUS Wheelchair-Mounted Manipulator: Developments Towards a Product Model. Kwee HH, Duimel JJ, Smits JJ, Tuinhof de Moed AA, Van Woerden JA, v.d. Kolk LW, *Proceedings of ICAART '88*, Montreal, 460-461, 1988.

The MANUS Wheelchair-Mounted Manipulator. Kwee HH, Duimel JJ, Smits JJ, Tuinhof de Moed AA, Van Woerden JA, v.d. Kolk LW, *First International Workshop on Robotic Applications in Medical and Health Care*, Ottawa, 1988.

Jobs with Robots for Disabled People

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—This is a feasibility study for developing jobs for motor-disabled people within a flexible automated production environment utilizing an experimental installation, and including an introduction to working conditions (primarily a sheltered workshop).

Progress—A student from the Department of Flexible Production Automation in Delft has, within the framework of his studies in Boston, cooperated in a new design (redesign) of the control language CALVIN. Problems with the robot (RTX of UMI, Ltd.) have delayed the implementation of CALVIN into the IRV-robot and the construction of a demonstration set-up. A study begun in 1988, into the possibilities of using the Brugwerkplaats at the Job Creation Centre, Oostelijk Zuid-Limburg as a trial workshop, will be concluded soon.

Future Plans—Supplementary sponsoring from industrial disability funds will be requested. Should supplementary sponsoring be obtained, two trial jobs will be arranged with companies where technical, ergonomic, economic, and social aspects will be evaluated in context.

This study is being conducted in cooperation with the Delft University of Technology, Department of Product Automation; Tufts Rehabilitation Center; and the Job Creation Centre, Oostelijk Zuid-Limburg.

Mobile Rehabilitation Robotics

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Sponsors: *University of Michigan Medical Center; College of Engineering, University of Michigan*

Purpose—The Mobile Rehabilitation Robotics Project, a joint venture between the Rehabilitation Engineering Program at the Medical Center and the Robotics Systems Division in the College of Engineering, is involved in the development of an intelligent, autonomous mobile robot. The goal is to develop a truly independent mobile robot that can not only pass from one point in its environment to another while avoiding random obstacles, but also follow or guide an individual to a desired location. Such a robot will be able to carry a variety of environmental manipulators such as robotic arms, environmental control units, or other assistive systems. A computer-based functional task guidance system has been chosen as the first of such devices to be mounted on the robot. This task guidance system for people with cognitive difficulties has been developed within the Department of Physical Medicine and Rehabilitation. Development and implementation of the mobile robot base will enable the task guidance system to become mobile and thereby greatly increase the range and type of user applications.

Progress—A mobile robot system is under development in the Robot Systems Division of the University of Michigan College of Engineering. This mobile robot utilizes an obstacle avoidance system comprising a ring of ultrasonic sensors mounted on a Cybernation K2A robot together with custom-developed software. As obstacles come within the ultrasonic sensor range (approximately 10 feet), the avoidance algorithm makes decisions allowing the robot to negotiate the obstacle, while continuing to proceed in the direction of the target. The algorithm is also designed to recognize and rescue the robot from dead end "trap" conditions. Testing with various unmapped obstacles (including moving ones), has shown the robot system capable of traveling at approximate normal walking speeds and reaching the desired target with a "reasonable" path.

Preliminary Results—An additional mobile robot manufactured by the Denning Company has been procured which will be dedicated to the implementation of the mobile robot task guidance system. The Denning system includes an integrated ultrasonic sensor ring and a radio link. It is currently being refitted to run the software developed at the University of Michigan for obstacle avoidance in fast-moving robots. This refitting includes the exchange of the Denning robot onboard computer with a higher performance model.

Future Plans—Planned objectives include the development of a nonphysical link between the robot and its "user," which allows for unique identification of that individual, as compared to other individuals or objects present in the environment. The robot will then be able to lead or follow a person to whom it is assigned. Also planned is the further development of global path planning software and its integration with obstacle avoidance algorithms. Following the attainment of these objectives, the mobile robot will be outfitted and interfaced with the previously-developed task guidance system. The first application of the mobile robot task guidance system will take place at the Ann Arbor VA Medical Center Nursing Home Care Unit where it will be employed in guiding patients, who could not otherwise function independently, through their daily routines. Another application being considered includes mounting of a robotic arm and manipulator for assisting handicapped users in daily living and vocational activities.

C. Communication Methods and Systems

Evaluation of the Regency Park Toy Control Program

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Sponsor: *Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The Regency Park Toy Control Program was designed and developed to train skills specific to the needs of children who will use single switches for computer/communication device access. At the Regency Park Centre we have realized the importance of introducing these skills as early in a child's life as possible. A computer program was designed that provides tasks relevant to single-switch access training and a reward appropriate to the child's age and environment (i.e., a battery-operated toy). A single switch is connected to the Apple IIe games port, and if the child performs the task presented on the computer screen, the toy is switched on for a predetermined time.

The evaluation is measuring two variables: 1) attention to task; and, 2) number of correct switching responses over a 5-minute session. Each of 10 children, in the 3-5 years (developmental) age range is presented with three versions of the program: 1) a screen presentation of tasks with a toy reward; 2) a screen presentation of tasks with a screen graphics reward; and, 3) therapist presentation of tasks with a therapist social reward.

Preliminary Results—Testing of 10 children is currently underway. Results of a pilot study show that a toy and screen reward presented simultaneously was more effective than either toy or screen individually.

Future Plans/Implications—The Toy Control Program is currently available from Regency Park Centre. Results of the full study will be presented for publication by June 1989.

Information Technology for the Disabled

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Sponsor: *Digital Equipment Ltd.*

Purpose—A major part of this work will be an extension of a project into the application of conversational analysis to the design of computer-based systems for the speech-impaired.

Progress—This communication system will allow a user to navigate through conversations by presenting them with a limited number of choices for their next utterance which is automatically selected from a large store of previously-prepared text. Thus, unlike current phrase storage devices, the user will not have to remember a large number of codes or mnemonics in order to access the appropriate phrase. This will give a much higher communication rate than is possible using current devices.

The project will also involve exploration of methods which enable the user to convey individual personality and current mood (e.g., happy, angry, sad).

Although, when using this system, the major part of a conversation will be carried out by pressing a single key (or one of a small number of keys), to produce entire phrases, there will also be a facility to make up an entirely new phrase. This facility will be based on "PAL," a Predictive-Adaptive-Lexicon based typing aid for severely physically disabled people already developed at the Microcomputer Centre. This significantly speeds up the typing of text by predicting words based on general frequency and recent use by the user.

Development of Flexible and Modular Systems for Automatic Speech Synthesis with the Use of Linguistic and Phonetic "Knowledge"

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The following aims were formulated for this project: 1) to obtain linguistic and phonetic knowledge for the realization of an automatic text-to-speech converter; 2) to develop "tools" which will make it possible to implement the obtained knowledge in a machine; 3) to develop a machine which is characterized by a high measure of flexibility; 4) to construct a text-to-speech converter which operates on a real-time basis; and, 5) to construct actual systems that can be used as an aid by disabled people.

Results—The project has lead to results that are important for text-to-speech conversion. In the linguistic field, sets of rules have been developed for the conversion of letter-to-sound representation. In the phonetic field, knowledge was obtained by studying natural speech utterances which made it clear as to what was the most relevant information enclosed in the speech signal. The developed "tool" is a compiler that converts linguistic and phonetic rules into a PASCAL program.

Flexibility was achieved by using a strictly modular approach for the text-to-speech converter and by keeping linguistic and phonetic knowledge separate. In cooperation with the Delft University of Technology, the text-to-speech converter was implemented on a plug-in board for an IBM-PC or compatible computer. Thus, it is now possible to convert text-to-speech in real time. This means that a user, after offering a normally-spelled text, will be unaware of any computing processes that take care of pronouncing the utterance. Resus b.v. has developed applications of the speech board for commercial purposes.

This project was conducted in cooperation with Delft University of Technology and Resus b.v. Hendrick Ido Ambacht.

Publications Resulting from This Research

A New Synthesis Model for an Allophone-Based Text-to-Speech System. Boves L, Kerkhoff J, Loman H, *Proceedings, European Conference on Speech Technology II*, J. Laver and M.A. Jack (Eds.), 385-388, 1987.

Automatic Text-to-Speech Synthesis by Allophones. Boves L, Kerkhoff J, Loman H, Van Son N, *IFN-Proceedings II* 24-26, 1987.

Praktisch Gesproken. De Parser-generator: een Ingebouwde Programmeur: Part 3. Kerkhoff J, Boves L, *Databus* 1987.

Speech-Controlled Environment Control

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project was to develop a speech-controlled aid to assist seriously-disabled people operate various appliances in their environment (such as telephone, TV, radio, doors, curtains, page-turning-devices, lights, etc.). The system had to be constructed modularly in order to fit all appliances.

Results—The appliance is now available. The project was conducted in cooperation with Huka, Oldenzaal.

Input Methods for Communication

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of the project is to increase the speed of communication utilizing various input systems recently developed through modern techniques. The methods to be used are based on the frequency with which certain letter sequences or words occur in various kinds of texts. At a later stage, syntax techniques that can be described as artificial intelligence, will also be used. The current project aims at the development of: 1) an input system that uses a predictor which automatically completes words after one or more letters have been given; and, 2) an input system that can work with a small number of keys (e.g., the 12-key telephone system), where there are more characters on one key and yet one touch per letter is enough (the computer will do the rest).

Progress—An analysis was made, based on a thorough inventory of international research, and with the cooperation of research groups in the United Kingdom and the United States.

Various kinds of texts (spoken and written) were analyzed, such as governmental documents, EEC documents, newspapers, and books. The frequency counts yielded substantial differences.

A Dutch version of the WRITE System was developed, with which parts of words can be given with one stroke of a key. For systems with a small number of keys, a decoding program was developed that would automatically choose the correct character out of the 3 present on one key, so that only one touch per letter is sufficient. Finally, an evaluation experiment was prepared that will clarify the specific advantages and disadvantages of various input systems (Dutch WRITE, the English PAL, the multi-character key system, and a combination of PAL and WRITE).

This project is being conducted in cooperation with Catholic University Nijmegen, Department of Phonetics (Dr. L. Boves); Tufts University, Rehabilitation Engineering Centre, Boston, MA (Dr. R.A. Foulds); A.I. Dupont Institute, Rehabilitation Engineering Centre, Wilmington, DE (Dr. R.A. Foulds); and the University of Dundee, Microelectronics Centre, Dundee (A.F. Newell).

Publications Resulting from This Research

First Report on Input Methods for Communication Aids for the Handicapped. Van Balkom LJM, Soede M, *IRV* Hoensbroek: IRV/10 Doc, 1987.

Linguistic Efficient Communication Systems: Consideration of Feedback Principle. Van Balkom HLM, Soede M, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:133-135, 1987.

Lexical Prediction Techniques Applied to Reduce Motor Requirements for Augmentative Communication. Foulds RA, Soede M, Van Balkom HLM, Boves L, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA 7:115-117, 1987.

Statistical Disambiguation of Multi-Character Keys Applied to Reduce Motor Requirements for Augmentative and Alternative Communication. Foulds RA, Soede M, Van Balkom HLM, *Augment Alterna Commun* 192-195, 1987.

Evaluation of Optics for Visual Communication by Voiceless People

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Our purpose was to get the prism communicator to speech-impaired people and establish a small production line to supply this communicator. This purpose raises two questions: 1) Can the prism communicator generally be used for a spelling conversation with untrained others? and, 2) What acceptance problems do patients and partners have concerning the prism communicator?

Results—Question One can be answered in the affirmative. Question Two cannot be answered that unambiguously. A small production line has been established with sales via the firm of Tieman BV in Rockanje. This has also resulted in sales abroad (three items went to New Castle Health).

There is a videotape with instructions for the user with Dutch text. For the benefit of voiceless people, prism communicators may also, as long as supplies last, be rented at some six institutions throughout The Netherlands. As a result of the wishes of ergotherapists/speech therapists for a lighter prism communicator, the prism folio communicator was developed.

This project was completed with the cooperation of the Institute for Rehabilitation Research in Hoensbroek.

Publications Resulting from This Research

Scrabble Spelen via de Prismacommunicator. Ten Kate JH. *ALS Nieuwsbrief* 7(1):36-37, 1987.

Gebruik van de Prismacommunicator voor de Platliggende Stemloze Patient. Ten Kate JH. *ALS Nieuwsbrief* 7(2):46-47, 1987.

Evaluatie Prismacommunicator-Een Veldevaluatie. Oostinj-Verschuur WT, Ten Kate JH, Speth-Lemmens IMAF. *Report IRV/11 Doc 87*. Hoensbroek: Institute for Rehabilitation Research, 1987.

Neuromuscular Assessment for Assistive Communication Device

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—In 1985, we embarked upon a complex evaluation program with a severely handicapped non-vocal cerebral palsy patient, with the goal of developing a specialized interface for use with an assistive communication device.

Progress—To accomplish this, a motor control assessment procedure (MCAP), combining clinical observation methods with computer-aided motion analysis, was developed. MCAP examined two types of information which may be used for device control: myoelectric activity at various muscle sites, and the displacement of body parts in space. Special assessment tasks were used to systematically evaluate the patient's motor abilities in quantitative terms which lent themselves to the design and construction of assistive devices.

Results—In 1986, we completed the motor control assessment procedure for this particular patient, using our sophisticated WATSMART motion analysis system. At that time, analysis of both myoelectric and head displacement data indicated that the patient possessed limited, but possibly useful, proportional control of his head and neck region. It was envisioned that he could significantly improve his rate of communication by incorporating an interface that utilized a proportional mode of control. This would upgrade his existing communications device, which slowly selects single letters from a computer screen via a head-operated switch. The major obstacle in utilizing a proportional controller for this patient lay in his inability to maintain a stable body reference posture required by such devices.

In early 1987, the patient was admitted for corrective surgery to alleviate problems related to progressive spinal curvature and seating posture. A post-surgical evaluation using MCAP in the Fall of 1987 revealed that, in addition to improving his postural and seating problems, the patient had gained additional proportional control of his head as a result of surgery.

Future Plans/Implications—These improvements may provide the patient with the postural stability necessary for implementation of a practical, proportionally-controlled communications interface. At the present time, we are augmenting our MCAP protocols to measure other parameters relating to motor control assessment. Strength and endurance of various control sites will be quantified using force and fatigue assessment techniques developed at our laboratory. These additional measurements will help give us a better overall representation of a subject's motor control capabilities.

Publications Resulting from This Research

New Motor Control Assessment Techniques for Evaluating Individuals with Severe Handicaps: A Case Study. Rudin NJ, Gilmore LD, Roy SH, DeLuca CJ, *J Rehabil Res Dev* 24(3): 57-74, 1987.

PC Transparent Keyboard for Head, Hand, and Mouth Stick Users with Voice-to-Text-Mode

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project addresses those who, as the result of neurological impairment, cannot use a standard keyboard in the way for which it was designed. These people are restricted to activating the keyboard one key at a time, with a single digit, i.e., finger, hand stick, mouth stick, or head stick. Various techniques, such as positioning templates, have been designed to improve the disabled person's use of a standard keyboard. Our purpose is directed toward designing a totally new keyboard that would use the abilities of the disabled person.

Progress—A-two-degree-of-freedom (2DOF) keyboard has been built and used with IBM-compatible personal computers (PCs). The system uses an Intel 8031 microcontroller for intelligence and a two-line 24-character-per-line liquid crystal display (LCD). The circuitry has been implemented in printed circuit form and a manufacturing prototype has been constructed. A text-to-voice device has been added, and additional software written to allow four modes of operation. The resulting keyboard also may be used as a communicator. The keyboard is transparent to the PC to which it is attached, allowing any software available to the able-bodied to be used by the disabled.

Speech Output. An optional text-to-speech circuit has been added which speaks the character assigned to each key when the key is initialized and when the key is sent. Three-switch selectable modes are available: *Mode 0*—The character(s) are spoken when initialized and spoken again with the word "Sent" appended when the key is selected and sent to the computer. *Mode 1*—Speech Composition Mode. Approximately 2,000 characters can be input with no speech occurring until the ENTER key is selected, at which time the text is spoken. *Mode 2*—The character(s) are spoken only when selected, and have the word "Sent" appended. *Mode 3*—The speech option is not initialized.

Stand Alone Capability. The keyboard draws its power from the computer (approximately 300 milliamps is required). If the keyboard is being used as a teaching tool or in a communications mode, it can operate alone with an optional power supply.

Summary of Special Features of the 2DOF Keyboard. The keyboard has 90 physical keys arranged in 5 horizontal rows with 18 keys on each row. There are 4 keysets with 90 keys on each keyset which can be selected by any of the 4 keys at the four corners of the keyboard. These keys are referred to as "Keyset-select-keys."

Each key, of the 360 available keys, can be assigned up to 16 characters. Up to 16 keystrokes on the regular keyboard can be assigned to a single key on the 2DOF keyboard in the form of small phrases or parts of commonly-used words. This saves the number of key-hits required in order to type a word or phrase.

Special functions eliminate some problems that disabled people face, such as the need to hit two keys at the same time (i.e., CONTROL plus any other key, or the SHIFT key plus any letter key). This problem is eliminated on this keyboard by having special function keys that permit the CONTROL, SHIFT, and ALTERNATE keys to be selected as toggle keys. Another special function key causes the first character of the next selected key to be shifted. Each key is a two-way action key, meaning that a key has to be initialized first and then selected before the character(s) assigned to that key are sent to the computer. This eliminates the problem of accidental selection of keys.

There is a two-line-by-24-character display that gives information about the meaning and location of each key on the keyboard, and a speech circuit which can be operated in different speech modes. Every time a key is initialized or selected, depending on the active speech mode, the speech circuit says the character(s) or phrase that is assigned to that key. Another speech mode allows the user to type up to 2,000 characters and have the speech synthesizer say the whole phrase collection at once.

The 2DOF keyboard can be used as a stand alone communication device by making use of the display and the speech synthesizer. The meaning of each key on the keyboard is software programmable and the four keysets can be easily customized for the needs of each individual user.

Transparent Access to Windows 2.0 by Individuals with Physical Disabilities

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Sponsors: *National Institute on Disability and Rehabilitation Research; IBM Corporation; Office of Special Education Programs*

Purpose—This project is designed to provide access to the *Windows* operating system by persons with physical disabilities. Access will be provided by implementing the One Finger, Mouse Keys, and General Input Device Interface (GIDI) features under Windows.

Progress—The One Finger and Mouse Keys features have already been implemented. The GIDI is currently being developed.

Future Plans—It is expected that all programming will be completed in 1988. There are also plans to work with the Microsoft Corporation to explore making these features a standard part of the Windows operating system.

Considerations in the Design of Computers and Operating Systems to Increase Their Accessibility to Persons with Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this project is to facilitate exchange and interaction of ideas on making computers accessible to individuals with disabilities. Input from manufacturers (both of computers and of specialized equipment), researchers, and consumers is used to gain new understanding of areas in which product development is necessary. The task force involved in this project is also charged with comparing and contrasting actual guidelines and guidelines established by the task force. This project supports the efforts of the Industry/Government Initiative, started in 1984 to support work by the White House, the Office of Special Education and Rehabilitation Services (OSERS), and the National Institute on Disability and Rehabilitation Research (NIDRR).

Progress—Several versions of a document outlining "Considerations in the Design of Computers" (formerly "Guidelines") have been completed. This document reflects the combined input of industry, researchers, and consumers, and provides a revised summary of the problems, populations affected, priorities, and possible solution strategies. It is updated and modified to reflect changing trends and priorities. The most recent version (Version 4.2) is dated May, 1988.

In 1987, members of the Task Force provided input to the NIDRR and General Service Administration (GSA) during the development of procurement guidelines to increase the accessibility of electronic office equipment. The Task Force contributed ideas and expertise from its earlier work and provided specific review of NIDRR and GSA proposed guidelines. This project has resulted in facilitating the computer industry in their consideration of design and manufacturing of products to optimize the access of computers to persons with disabilities by highlighting need and suggesting economical and feasible design ideas.

Future Plans—The project is expected to continue in its supportive role. The next revision of the Considerations Document is scheduled for May, 1990.

Publications Resulting from This Research

Features to Increase the Accessibility of Computers by Persons with Disabilities. Vanderheiden GC, Lee CC, Scadden LA, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:750-752, 1987.

Advance Executive Summary of the Considerations Document (Version 3.0). Vanderheiden GC, Lee CC, University of WI-Madison: Trace Center, 1987.

Considerations in the Design of Computers and Information Processing Systems to Increase Their Access by Persons with Disabilities (Version 4.2). Vanderheiden GC, Lee CC, University of WI-Madison: Trace Center, 1988.

Trace One-Screen Alternative Keyboard for Headpointing Typing into IBM-PC and Compatible Computers

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The One-Screen program provides an alternative keyboard for IBM-PC and compatible computer systems by providing transparent access to IBM computer programs that use the standard keyboard for input and use any Color Graphic Adaptor (CGA) graphics modes. This alternative keyboard is unique in that application programs and the One-Screen on-screen keyboard run on the same screen. Word prediction tables are also included to increase typing rates. The One-Screen program can be used with any mouse-compatible pointer (including the Freewheel Pointer from Pointer Systems of Burlington, VT) or the Long Range Optical Pointer (LROP) available from WORDS+ in Lancaster, CA. The One-Screen program has been transferred to WORDS+ and Pointer Systems for commercial distribution.

Publications Resulting from This Research

One-Screen Multiplexed Keyboard for Transparent Access to Standard IBM-PC Software. Gunderson JG, Vanderheiden GC, *Proceedings of ICAART '88*, Montreal, 378-379, 1988.

Software Keyboard-Emulating Interfaces for IBM-PC and Apple Macintosh

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Our purpose is to develop keyboard-emulating interfaces implemented in software for IBM-PC and compatibles and Apple Macintosh computers. These programs act as an interface to allow a device that can send serial ASCII output (such as a communication aid) to perform the functions of standard input devices such as keyboards. The software interface is less bulky and less expensive to manufacture than a hardware interface.

Progress—The IBM-PC keyboard emulating interface (KEI) programming is complete, and has been transferred to Prentke Romich Company of Wooster, OH. Prentke Romich will begin production soon. The KEI for the Macintosh is currently under development.

Future Plans—We plan to complete the software interface for the Macintosh, which will allow a serial ASCII device to control the operation of the keyboard. When complete, this program will also be transferred to a commercial vendor.

Dissemination of Information on Communication, Control and Computer Access

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Sponsors: *National Institute on Disability and Rehabilitation Research; University of Wisconsin-Madison*

Purpose—The activities and projects in this section of the Trace Center are aimed at disseminating current information about products, resources, and techniques available in the areas of communication, control and computer access, and identifying optimal methods for information dissemination.

Progress—Fifty-four titles were available from the Trace Center Reprint Service this year, and approximately 7,000 publications were distributed. The Information and Referral Service continues to respond to an annual average of 1,200 direct inquiries. These are answered with individual letters and/or compiled information summaries on particular topics ("Quick Sheets").

The Trace Center also continues to maintain TraceBase, a computerized database listing products, service organizations, and information resources. Entries are added and updated on a regular basis. The product listings in this database are used as a source for *The Rehabilitation ResourceBook Series: Communication, Control and Computer Access for Disabled and Elderly Individuals.* An update to the initial three-volume set was published in the Spring of 1988. This one-volume update contained only products not listed the year before, plus cross reference indexes for all four volumes. The update contained over 300 products.

Future Plans—Another complete edition of the ResourceBook Series is slated for 1989. The Reprint Series titles will also continue to be updated annually. An information request tracking system has been instituted for future compilation and analysis of data on requests received.

Publications Resulting from This Research

Rehab/Education ResourceBook Series, ResourceBook 4: Update to Books 1, 2 and 3. Borden PA, Vanderheiden GC, (Eds.), University of WI-Madison: Trace Center, 1988.

Pointing Devices for the Movement Impaired: Development of an Evaluation Tool

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Purpose—Although input pointing devices (joysticks, lightpens, mice, tablets, touchpads, touchscreens, trackballs, etc.), and new computer operating systems utilizing graphics-based iconic images can make computers easier to learn and more efficient for the fully-abled portion of the population, these devices can hamper use by individuals with physical impairments such as motor coordination problems, paralysis, or spasticity. Assistive computer access devices are available for motor-impaired individuals. However, many of these rely on keyboard input strategies, or they are so slow that their users are unable to participate meaningfully or compete in regular education or employment settings. Alternative mouse devices such as head-pointers are becoming commercially available, intended to help mildly-to-moderately impaired individuals, especially those with cerebral palsy or spinal injuries.

Before the effectiveness of an alternate input device for a person with a particular motor impairment can be evaluated, it is necessary to have some objective measure of performance. Since each disability is a personal issue, to determine which one out of a number of potential strategies is most appropriate for an individual, it is necessary to have a method for comparing performance using these devices. Determining the optimum settings for a particular user also requires an objective measure that is reliable and should have predictive capabilities. The performance measures often used for comparing pointing devices intended for people with normal motor capabilities are speed and accuracy. The purpose of this study is to develop psychomotor tests for evaluating alternative input devices.

Progress—Software has been developed, tested, and experimental paradigms implemented for testing head-pointing devices and conventional mouse pointers. Experiments in progress include both non-impaired and movement-impaired subjects.

Cognitive Factors in Access to Computers and Electronic Devices

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this program of research is to analyze: 1) what makes a computer difficult to use, for ordinary users, and what adjustments are made by designers of computers in order to accommodate experienced and inexperienced computer users; 2) how presentation and reception of information are dealt with in currently existing computer adaptations designed for people with cognitive disabilities; and, 3) how cognitive factors in access to computers are applied to people with physical and sensory disabilities.

Progress—Literature reviews are underway for the development of a state-of-the-art paper focusing on cognitive access issues relating to computer use by disabled individuals.

Future Plans—Publication of a state-of-the-art paper on the subject, in consultation with other experts in the field. Other projects will include: 1) task analysis of steps involved in computer operation by people with different cognitive disabilities; 2) development and testing of design considerations for people with cognitive disabilities; and, 3) recommendations regarding how individuals with cognitive disabilities can be accommodated in the design of standard computer hardware and software.

Applications of Conversation Analysis to the Design of Communication Aids

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Sponsor: *None Listed*

Purpose—Most communication aids for non-speaking physically disabled people are designed to perform the primary task of message passing. While this is certainly a part of human communication, research in the field of conversation analysis has demonstrated that there are other purposes to conversation, which are of equal, or greater importance. In order for augmentative and alternative communication devices to be true conversation aids, this realization has to play a part in their design.

This research project has as its base a thorough survey of conversation analysis, including contributions from the fields of philosophy, sociology, anthropology, linguistics, education, psychology, and artificial intelligence. A number of important features of conversation have been highlighted: 1) the differences between spoken and written language; 2) the major role played by speech rate, rhythm, and intonation in conveying meaning; 3) the importance of speech acts that accomplish interactive goals, as opposed to messages, which relay information; 4) the ritualized nature of a large proportion of daily communication; and, 5) predictable structural features of discourse as well as ritualized "scripts."

Progress—The research project is drawing up a set of guidelines for the design of communication aids that will allow them to model natural conversational behavior. While some of these guidelines must await future technological improvements for their full realization, there is much that can be done with existing computer systems. As well as this work on a new structure for communication aids. the project is embodying the design guidelines in working prototypes. These have been christened CHAT (Conversation Helped by Automatic Talk) and are implemented using commercially-available hardware.

Speech Synthesis Systems

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Sponsor: *None Listed*

Purpose—Synthetic speech is an important output medium for communication systems for the handicapped, particularly when a communication system is used for conversation purposes.

Speech synthesis is therefore being investigated with a view to improving the quality and control of synthesis devices in such communication systems. While existing speech synthesis technology including text-to-speech systems, can give relatively acceptable and comprehensible speech quality, there is usually restriction on the range of vocal types (e.g., male or female, child or adult) and the mode of expression which can be achieved. It is intended to improve the control of such features, and to integrate this control into the communication system of a handicapped or speech-impaired person.

Toward the Development of an Accessible Computer Workstation and School Desk for Use in the Classroom

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Sponsors: *Ontario Ministry of Education; The Hugh MacMillan Medical Centre*

Purpose—Our purpose was to work toward developing a fully accessible workstation and school desk which would accommodate both the educational and therapeutic needs of physically disabled students within the school classroom.

Commercially available computer workstations generally do not facilitate access, nor do they promote proper positioning for the physically disabled student. Most tables are designed to be used by one individual in a home or office setting, therefore, they are often not readily adjustable, if at all. This type of table is impractical in the classroom where many students with special needs may be required to use the same computer each day.

In response to this, a multidisciplinary team from the Hugh MacMillan Medical Centre and the Hugh MacMillan Centre School has undertaken a project to develop a fully accessible computer workstation and school desk which will accommodate both the educational and therapeutic needs of physically disabled students within the classroom.

Results—A modular workstation was conceived to satisfy the broad range of needs of students with physical disabilities. Such an approach permitted the appropriate components to be assembled and adjusted to match individual needs.

The foundation of the design was an adjustable work surface that accommodated the basic hardware (computer, monitor, keyboard, and disk drive) as well as a work space for a textbook or other material. Other modular components would build onto this basic unit to permit greater flexibility in positioning equipment, provide forearm support, accommodate alternative interfaces, remote keyboards, and a printer.

The basic unit was assessed by teachers, teaching assistants, and therapists over four 3-week trials. Participants were asked to comment on the performance of the prototype unit when used by their students as a computer table and as a school desk in the classroom.

Results—Results of the evaluations indicated that the basic unit performed favorably. However, development of other modular components was recognized as being needed to complete the workstation.

Development of a Patient-Computer Interfacing System

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Purpose—For those disabled computer users who cannot use a normal keyboard, there are a variety of alternative input systems. But, these are commonly: 1) incompatible with each other; 2) compatible with only one microcomputer; and, 3) difficult to connect and configure without technical training.

As a result, many of the alternative input systems in occupational therapy departments and special schools are under-utilized. In addition, the wide range of hardware and software, and the variety of disabilities to which these devices can be applied, means that identifying an optimum system for a particular client is a cumbersome, lengthy, and costly process.

It is intended to address this problem of incompatibility by developing a patient-computer interfacing system. This will incorporate a carefully selected range of commercially available components configured in an easily interchangeable form, with some additional interface modules and switch mountings. It will allow the therapist and client to experiment quickly and effectively, in a way that is not currently possible, unhindered by the present technical constraints. This will ensure that the final choice of system components is dependent on the clients' abilities and not on what is immediately available or can be easily connected together.

Progress—For the project, it is necessary to develop an adaptable Keyboard Emulating Interface (KEI) which will allow a variety of alternative input systems to be rapidly interchanged. This KEI will accept input from a variety of alternative input systems and will also be capable of conforming to existing proposed interconnection standards. For this degree of flexibility, a programmable central module is necessary, and a commercially available single-board microcomputer, programmable in FORTH, is being used to provide a cost-effective solution. Initially, this has been designed to interface two alternative input systems with widely-differing interconnections (the Newtech Keymaster System and the Elfin CID System), simultaneously, to the Acorn BBC-B microcomputer.

Future Plans—It will now be developed further to permit connection to the IBM-XT microcomputer. However, the flexibility is such that the KEI could be connected to many other commercially available microcomputers and alternative input systems in future with only minor further developments. It will therefore fulfill a central role in the project.

Adaptive Predictive Communication Aid for the Disabled

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Sponsor: *Scottish Home and Health Department; the Spastics Society of Scotland*

Purpose—A microcomputer-based aid has been developed to assist disabled persons to use a typewriter, word processor, or other text-orientated device.

Progress—The system improves the typing efficiency of a disabled person by predicting required words to the user before the complete word has to be typed. The user can easily select from a list of predicted items, and reduce typing workload by as much as 50 percent, depending on the nature of text being typed. The system optimizes prediction efficiency by adapting to the vocabulary of the user, maintaining a dynamic lexicon representing current word usage.

A version of the predictive system has been mounted on a compact portable computer suitable for use by a wheelchair user with limited upper limb function. Another version has been equipped with a self-scanning interface appropriate for use by a quadriplegic.

This system has been well received by disabled people and researchers, and has been developed into a form suitable for manufacture and distribution in the commercial sector.

Communication Aids for the Neurologically-Involved Child and Young Adult in the School and Community

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Sponsors: *Scottish Home and Health Department; The Whitetop Foundation*

Purpose—PAL is a Predictive Adaptive Text input device which reduces the keying needs of physically disabled people when using a microcomputer as a communication aid.

This project is an integrated research, development, and clinical evaluation program. The objectives are as follows: 1) to analyze speech-impaired clients in Tayside with respect to their degree of physical disability and the corresponding residual function available for control of a transducer and operation of a communication system; 2) to review and evaluate the design of existing transducers and characterize the nature of the required physical input needed to operate them; 3) to take the current Dundee (PAL) system as a basis and develop facilities that take full advantage of the increasing power of microcomputers to improve the quality of communication; 4) to develop or specify improved transducers and investigate alternative methods which would permit more complex forms of input. This investigation will include a study on the effect of posture and seating on switch operation; and, 5) to implement the improved PAL system on a small number of patients, utilizing the new transducers and conduct a clinical trial of their use and function.

Progress—A survey was designed to describe the communicative and physical abilities of clients who had communication disorders. The 2,556 clients were in contact with speech therapists, voluntary organizations, health visitors, and general practitioners in Tayside. The results of the survey have been stored on a database.

PAL. The development of PAL has followed three lines: 1) improvement of the predictive algorithm by the use of syntax and special processing of function words; 2) linguistic expansion techniques; and, 3) improvement of the implementation.

Assessment. Standard documentation has been developed to collate information about potential users which had been gathered by professionals already involved with the clients.

Evaluation. Techniques are being evolved for the evaluation of the predictive system focusing on the following three aspects of communication: 1) rate of communication; 2) quality of communication; and, 3) subject/listener satisfaction with the augmentative system.

Future Plans—In the future: 1) a protocol will be developed for the assessment of the physical abilities of a non-communicative person in terms of the residual function available to operate a communication system; 2) existing switch systems will be evaluated and characterized in terms of the nature of their physical input; 3) an investigation will be carried out on the effects that body posture and positioning of switches have on the performance of switch/person match; 4) further investigations into the way in which context may be used to improve predictions will be carried out. "Recency" already goes some way towards achieving this aim; however, it is hoped to exploit the "co-occurrence" of particular words in past usage when compiling prediction lists; 5) a protocol will be developed for the evaluation of the switch/person match and will be integrated with the evaluation protocol currently being developed for the PAL system. These protocols will then be combined and implemented in a clinical trial with a small number of clients; and, 6) the topic of a two-way communication environment will also be investigated during the latter stages of the project.

Publications Resulting from This Research

The Use of Syntax in a Predictive Communication Aid for the Physically Handicapped. Swiffin AL, Arnott JL, Newell AF, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:124-126, 1987.

Adaptive and Predictive Techniques in a Communication Prosthesis. Swiffin AF, Arnott JL, Pickering JA, Newell AF, *Augment Altern Commun* 3(4):181-191, 1987.

Communication Aids and Voice Synthesis. Brophy B, Arnott JL, Newell AF, *Proceedings of the European Conference on Speech Technology*, Edinburgh, 361-364, 1987.

Computational Linguistic Techniques in Computer Systems for the Speech-Impaired

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Sponsor: *The Spastics Society of Scotland*

Purpose—This grant is part of the work on the development of communication systems for the speech-impaired. In particular, the research worker is investigating how various techniques which have been developed in computational linguistics and discourse analysis can be applied to the very practical problems of developing an efficient and effective communication system for people with very limited physical movement.

As with the other work in the Microcomputer Centre, the design criteria will include speed of operation, ease of operation, and use of commercially available components.

D. Private/Public Programs

New Models for the Delivery of Personal Assistance Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Independence for hundreds of thousands of Americans is contingent upon the availability of reliable sources of personal assistance. Personal assistance can enable even those with the most severe disabilities to have opportunities for self-direction and productivity in a setting of their own choice. Many people who need these services, however, do not receive them because of lack of awareness of what personal assistance (also known as attendant services) is, unavailability of appropriate services, and, most often, lack of funds to purchase the needed services. While this issue is inestimably critical to a substantial segment of the population, it has not been thoroughly subjected to scientific examination or gained the attention of public policy makers.

Progress—To address this critical issue, the Independent Living Research Utilization (ILRU) Program was recently awarded a grant by the National Institute on Disability and Rehabilitation Research to conduct a research project that examines existing types of helping systems and seeks answers to questions such as: How do individuals with disabilities meet their needs for personal assistance? What is the benefit to the consumer? What approaches to personal assistance services maximize the benefit? How can the most effective and efficient systems be replicated nationally? How can resources be generated or reallocated to support these services? What combination of federal, state, and local actions facilitates growth of this service?

This project brings together tools of empirical research and program evaluation to reach increased levels of understanding about how the adequacy of personal assistance services determines the functioning and quality of life of persons with severe disabilities and how their need for personal assistance can best be met.

Parameters of Independent Living Programs: A Longitudinal Study

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Sponsor: *The Institute for Rehabilitation and Research*

Purpose—This study builds on three previous comprehensive descriptive studies of independent living programs conducted by the Independent Living Research Utilization (ILRU) over the past nine years. The purpose to maintain a database on the status of independent living programs nationally and, through analysis, identify trends in their development, the emergence of new problems, solu tions for the delivery of independent living services, and changes in the characteristics of consumers of these services.

Progress—The survey used in previous studies by ILRU has been revised and refined using input from senior project consultants. The survey instrument was mailed to each of the more than 300 programs listed in the ILRU Directory of Independent Living Programs. Information was solicited concerning populations served, services provided, characteristics of service providers, methods by which services are provided and programs administered, sources of funding, and relationships between programs and their communities. The response rate was 50 percent for the full survey, with an additional 20 percent for an abbreviated version of the questionnaire. Profiles of each program responding to the full length survey have been published in the *ILRU Registry of Independent Living Centers*. Data were coded and entered into the computer, creating the ILRU National Database on ILPs. This computerized resource has proven to be quite rich. Analytic techniques, such as frequencies, cross-tabulations, chi squares, correlations, analyses of variance, and regression analyses have yielded some significant findings. These findings have been submitted at the request of *American Rehabilitation* and are being prepared in more detail for submission to the *Journal of Rehabilitation*.

Preliminary Results—Analysis of this database is in progress. The first examination of the data addressed questions of compliance with requirements for consumer control of independent living centers. Results indicated that levels of compliance with key requirements of Title VII, the independent living provision of the 1978 Rehabilitation Act, are quite low. Only 51 percent of programs receiving funds meet requirements for consumer involvement in direction, management, and service delivery. There was no relationship between compliance and receipt of Title VII funds or amount of Title VII funds received. It was also shown that complying programs offer significantly more services and served significantly more persons than non-complying programs. These findings have strong implications for federal policy and funding in the independent living area.

Analyses in progress address the effects of age, budget size, and degree of consumer involvement on parameters of independent living centers. A longitudinal analysis is also underway comparing results of the 1984 and 1986 studies. In the remaining months of year three, the fourth administration of the survey will be implemented and the data entry process will begin.

The Directory of Independent Living Programs is updated and reissued approximately five times per year. The new Registry of Independent Living Programs has been completed and is currently being disseminated.

Future Plans—Research staff will continue to update the Directory and respond to specific inquiries with individualized data runs and reports. Analysis will continue on the ILRU National Database on Independent Living Programs. A major publication on the evolution of the independent living program model will be prepared and published.

VII. Functional Electrical Stimulation

A. General

Computer Models for Designing FES Systems for Paraplegic Mobility

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Sponsor: VA *Rehabilitation Research and Development Service (Project #B289-2RA)*

Purpose—Restoring motoric function to spinal cord injured persons by functional electrical stimulation (FES) of their paralyzed muscles has been explored for over 20 years. It has been demonstrated that muscles activated by FES can enable paraplegics to rise from a chair, stand, and walk. These pioneering efforts have identified, however, major technological problems prohibiting routine clinical prescription of FES as a means for paraplegics to regain function of their legs. One of these problems is the lack of computer models, both for designing FES systems to control standing and walking in paraplegics, and for determining the trade-offs among the alternative control-system designs. Knowledge obtained from studying these trade-offs should reduce the amount of experimentation needed to develop clinical FES systems for restoring mobility to paraplegics.

Our long-term objective is to develop computer tools to assist the rehabilitation team in designing user-specific FES-control systems so that paraplegics can stand and walk. We believe that computer models should be used symbiotically with experimentation to design such FES systems.

Progress—We have: 1) derived the equations specifying the dynamic properties of standing (2-D only) when induced by FES of paraplegic musculature. The dynamics derived are based on a 3 d-o-f sagittal-plane (2-D) representation of the body, the musculotendinoskeletal geometry of the lower extremities, and the dynamics of muscles excited by FES-type signals: pulse-width (or -amplitude), and pulse-interval modulation; 2) found a feedback joint-torque control that, according to computer simulations, ensures stability of this dynamical system to large perturbations (such as occur during arm movements with loads), and to large parameter uncertainties as well; 3) developed a method, based on muscle-energy minimization, that determines how muscles ought to be FES-excited to generate the required feedback torque; and, 4) implemented on a graphics workstation an "animated" display of this musculoskeletal representation of the body to visualize the simulated standing-paraplegic.

Future Plans—We propose to broaden our computer studies of FES-induced standing in paraplegics by simulating frontal-plane as well as sagittal-plane motion (i.e., 3-D motion), and to computer-implement a dynamical model and graphics simulation of FES-induced walking as well. Specifically, we propose: 1) to increase the complexity of our body-segmental and musculoskeletal computer model to allow for frontal plane and pelvic-torso motion and control; 2) to determine the sensitivity of standing stability in 3-D to feet placement, to the number, specificity, and strength of muscles stimulated, and to body-segment dynamical interactions; 3) to derive the dynamics for both the single- and double-support phases of walking in 3-D, to study the dynamics of walking, and to begin to synthesize feedback laws for FES-induced control of walking; and, 4) to determine the sensitivity of walking ability in 3-D to the number, specificity, and strength of muscles stimulated, to body-segmental dynamical interactions, and to the kinematic states at the instants of gait-phase transitions.

Electrical Stimulation of Paralyzed Muscle after Spinal Injury: Influence of Surface Electrical Stimulation on Muscle Strength, Endurance, Spasticity, Cross-Sectional Area and X-Ray Density and on Urodynamic and Psychological Factors

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B249-RA); Paralyzed Veterans of America (Vaughan Chapter and National Spinal Cord Research Foundation)*

Purpose and Methodology—We investigated the effects of a clinical reconditioning program involving surface electrical stimulation on quadriceps' strength, endurance, spasticity, cross-sectional area, and X-ray density in a large sample of spinal cord injured subjects. We also investigated changes in psychological profiles and urodynamics. We focused on the responses of groups of subjects, rather than on a case-by-case basis. Thirty-four individuals started in this study. Subjects received 1 to 3 initial evaluations of peak torque and the end torque left after 20 minutes of electrically-induced isometric quadriceps exercise, and of any volitional torque. The test stimuli were applied via water-soaked sponge-covered carbonized rubber electrodes and were a 20 Hz train of 100 mA, 400 μsec compensated monophasic pulses that were delivered in alternating fashion (2.5 sec on, 2.5 sec off) to each leg. Lower extremity spasticity was evaluated using the pendulum drop test. Prior to our reconditioning program, 23 subjects underwent CT scans at one-third and two-thirds the distance from the greater trochanter to the patella We assessed psychological status with a clinical interview and with three standardized tests: the Multidimensional Locus of Health Control (MLHC), the Profile of Mood States (POMS), and the Tennessee Self Concept Scale (TSCS).

Twenty-three subjects entered a 4-to-8-week reconditioning protocol where their quadriceps were stimulated during twice daily 20-minute sessions. Stimulus currents were set at 120 to 160 mA. The evaluations of torque and fatigue performed initially were repeated after both 4 and 8 weeks of reconditioning. Twenty-two subjects had 4-week evaluations, and 7 (plus one who missed his 4-week evaluation) had evaluations at 8 weeks. Follow-up CT scans were done on 15 subjects. Multivariate analysis of variance (ANOVA) analyses using time post-injury, level and completeness of lesion, presence or absence of volitional quadriceps torque, and age as grouping factors, were done to determine if any of these factors might serve to predict initial measures of torque, fatigue, spasticity, cross-sectional area and girth, as well as changes in these measures over the course of reconditioning. All of these subjects had follow-up psychological tests.

Results—*Baseline Measures.* Initial peak stimulated torque ranged from 0 to 46.4 N-m. Right baseline peak torque was significantly ($p \leq 0.05$) greater for quadriplegics than for paraplegics, for those with incomplete lesions versus complete lesions and for subjects with residual volitional torque. Peak and end torque did not depend on time post-injury. The end torque remaining after 20 minutes of stimulation was somewhat ($r = 0.76$) dependent on the peak torque and regressed at 12 percent of initial peak torque. In most cases, end torque was less than 25 percent of peak, and in no case did it exceed 50 percent. Left and right baseline measures of end torque were significantly greater for subjects with incomplete lesions than for those with complete lesions, and for those with residual volitional torque. No correlation was apparent between time post-injury and baseline peak or end torque. Seven of the 8 legs with over 35 percent torque remaining after 20 minutes of stimulation were from subjects with ≤ 1 year post-injury at the time of the initial test. With regard to spasticity, the drop test itself decreased spasticity, especially for subjects with shorter times post-injury. Spasticity was significantly reduced immediately post-stimulation (the reduction correlating with peak torque and initial spasticity); but the effect lasted less than 24 hours. The cross-sectional areas of the quadriceps and total thigh, especially in the complete paraplegics, were well below the range of the same areas for neurologically intact adult males, indicating a severe disuse atrophy. Neither upper girth or thigh cross-sectional area correlated well with quadriceps area and therefore were not good predictors of quadriceps cross-sectional area. Neither thigh girth nor thigh, quadriceps, or vastus lateralis cross-sectional areas were strongly correlated with stimulated peak or end torque. Subjects ≤1 year post-injury had significantly greater quadriceps cross-sectional areas than subjects more than 1 year post-injury. Quadriplegics had significantly greater left quadriceps areas than did paraplegics. Psychologically, the group of subjects exhibited a POMS "iceberg" profile. Quadriplegics initially attributed via the MLHC more health control to powerful others and to chance than did paraplegics; both had a diminished physical self-concept on the TSCS.

Measures after Reconditioning. After 4 weeks of stimulation, approximately one-third of the legs stimulated showed increases in peak torque over baseline values, one-third had diminished stimulated strength, and the remaining one-third showed no change. After 8 weeks, most remaining subjects showed increases in peak torque. Legs with the greatest base peak torque tended to have the greatest torque at 4 weeks, but they also tended to have the greatest decrement when compared to baseline. The major exception was for legs of subjects ≤1 year post-injury; 6 of these legs had strength gains in excess of 10 N-m. Also, legs with ≤4 N-m of stimulated baseline peak torque exhibited almost the same amount or less at week 4, indicating that a minimum response level might need be present for reconditioning to be successful. An increase in endurance over that seen at baseline was seen at 4 weeks, where end torque correlated ($r = 0.92$) with and regressed at 38 percent of peak torque. In contrast to baseline measures, most end torques were now between 25 and 50 percent of their peak torques, and 9 legs exceeded 50 percent. Half of the 8 subjects who exhibited some baseline voluntary quadriceps torque showed at least a two-fold increase in voluntary quadriceps torque after 4 weeks of reconditioning. The spasticity seen at 4 weeks correlated with that seen at baseline, but tended to increase especially in those who had a ≥5 N-m peak torque gain or in those with more baseline spasticity. Those less than 1 year post-injury had little change in spasticity. Increases in quadriceps spasticity correlated with significant decreases in bladder capacity, which is one measure of bladder spasticity. There was a significant overall change in quadriceps cross-sectional area, but not in girth, after reconditioning, that was independent of grouping factor. Psychologically, both tension and anger increased on the POMS for study participants. While some individuals showed marked changes in long-standing urodynamic profiles, reconditioning produced no consistent effect on urodynamics.

Implications—Our inability to achieve more universal gains in peak torque could be related to the method of reconditioning used or to its short duration (4 weeks), since strength increases were more noticeable after 8 weeks. Exercise at light loads is known to build endurance, not strength. Yet the gains achieved by those ≤1 year post-injury suggest that an early application of electrical stimulation might be indicated to maintain strength and muscle bulk. However, limb and bladder spasticity should be monitored to avoid exacerbating these conditions, and care should be taken with the psychological status of the individual.

Publications Resulting from This Research

Tomographic Atlas of Thigh Muscle in Persons with Spinal Cord Injury. Robinson CJ, Bolam JM, Chinoy M, Vacek M, Kett N, *Proceedings of the 13th NE Bioengineering Conference,* Abst 32.2, Philadelphia, PA, 1987.

Effect of Surface Electrical Stimulation on Spasticity in Spinal Cord Injured Patients. Kett NA, Robinson CJ, Bolam JM, *Proceedings of the 9th Annual Conference of the IEEE/Engineering in Medicine and Biology Society,* New York: IEEE Publications, 2:613-614, 1987.

Strength and Endurance Changes Following Electrical Stimulation of Muscles Paralyzed by Spinal Cord Injury. Robinson CJ, Kett NA, Bolam J, *Proceedings of ICAART '88,* Montreal, 322, 1988.

Predictive Factors for Quadriceps Reconditioning via Electrical Stimulation. Robinson CJ, Bolam JM, Kett NA, Engelmeier PK, Fruin RC, Nemchausky BA, *Advances in External Control of Human Extremities IX,* Dejan Popovic (Ed.), Belgrade: Yugoslav Committee for Electronics and Automation, 111-116, 1987.

Spasticity in Spinal Cord Injured Patients: I. Short-Term Effects of Surface Electrical Stimulation. Robinson CJ, Kett NA, Bolam JM, *Arch Phys Med Rehabil* 69:598-609, 1988.

EMG as Force-Feedback in Closed-Loop Functional Electrical Stimulation

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A310-RA)*

Purpose—Our purpose was to investigate closed-loop, functional neuromuscular stimulation (FNS) systems that might improve dynamic force and position control of paralyzed limbs. Myoelectric signal (MES) feedback was specifically investigated as a means of providing force feedback during isometric contractions. First, it was necessary to study the reliability of stimulated muscle contractions. Reports of muscle activation by both direct stimulation of the motor nerve and by intramuscular stimulation sometimes showed nonlinear stimulus-response characteristic (recruitment) curves, that were undesirable in neuromuscular control systems. The fascicular organization of the nerve as it branches to innervate the various ankle extensor muscles was found to have a significant influence on the recruitment order of the extensor muscles during both types of neuromuscular stimulation. When MESs were recorded individually from extensors according to the established motor innervation pattern, very high correlations between actual muscle tension during tetanic nerve stimulation and predicted tension based on MES recordings were obtained.

Progress—Electrical and force responses of the cat gastrocnemius muscle to tibial nerve (TN) and intramuscular stimulation were studied. Nonlinear recruitment curves (force versus stimulus amplitude) were produced in the gastrocnemius-soleus-plantaris muscle group in response to stimulation of the TN within a few cm of the muscle entry point. The response curves usually consisted of two regions in which force increased linearly with stimulus amplitude, separated by a "plateau" region in which force was relatively constant. Investigation of this phenomenon revealed that the two linear regions were associated with activation of separate neuromuscular compartments (lateral or medial gastrocnemius, plantaris, soleus, or subdivisions of those muscles). Furthermore, when the stimulated myoelectric responses from these compartments were plotted versus stimulus amplitude, the region of recruitment between threshold and saturation often did not appreciably overlap for different compartments, suggesting that the axons innervating those compartments were physically segregated within the nerve from axons innervating other compartments.

When composite myoelectric response curves were obtained by averaging responses recorded from each of the active compartments, correlation coefficients between force and stimulated myoelectric response were very high (up to $R^2 = 0.99$). By dividing the TN into its component bundles or fascicles and stimulating each in turn, it was possible to show that individual bundles innervate non-overlapping groups of muscle compartments, and that recruitment of the nerve bundles over different threshold ranges could account for the nonlinear force/stimulus response curves initially observed. While the finding of separate innervation of muscles or compartments by fascicles was not unexpected, the significance of the dependence of axonal threshold on fascicular organization has not, to our knowledge, been previously noted.

These single twitch results were used in predicting tension output during tetanic contractions. One fascicle of the TN of a chronically-paralyzed cat was stimulated with 30 pulses of varying amplitude at 50 Hz. Stimulation produced responses only in lateral gastrocnemius and soleus muscles. The peak MES amplitudes and single twitch force response curves were used to generate a simulated tetanic force curve using simple linear summation. For each stimulus, the twitch waveform was multiplied by the appropriate myoelectric response amplitude for each muscle and summed with an appropriate delay. Linear correlation coefficients (R^2) of about 0.98 were found between the actual and simulated tetanic force curves.

Conclusions—1) The compartmental organization of some muscle groups, by virtue of the segregation of the motor axons into fascicles within the nerve supplying them, may have a significant effect on their recruitment order during intramuscular or direct nerve stimulation. That is, there can be a preferential recruitment of all axons within a given fascicle before axons in other fascicles in the same nerve are activated. 2) Myoelectric responses can be used to predict the force generated during stimulated isometric muscle contractions.

Intramuscular Electrical Activation of the Diaphragm

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B186-2RA)*

Purpose—This project is aimed at the development of a system for functional electrical activation of the phrenic nerve using intramuscular electrodes implanted in the diaphragm. To that end, a prototype intramuscular diaphragm stimulating (IDS) electrode has been developed at the Applied Neural Control Laboratory under the supervision of Dr. J. Thomas Mortimer, PhD with the consultation of Dr. Thomas Kicher, PhD, from the Department of Mechanical and Aerospace Engineering at Case Western Reserve University. A technique for the implantation of these electrodes under direct observation with a laparoscope has been developed in collaboration with co-investigator Dr. Thomas A. Stellato, MD. In the past year, chronic experiments in a canine model using the prototype electrode have been performed at the Applied Neural Control Laboratory to test the safety and efficacy of long-term intramuscular activation of the phrenic nerve. In this progress report, we describe these experiments and summarize results as they pertain to the future application of this technique to treat chronic ventilatory insufficiency in humans.

Progress—Electrodes were implanted bilaterally in the diaphragms of six dogs who survived for 69 to 323 days. Five dogs underwent chronic bilateral stimulation for 61 to 183 days and one dog was used as an unstimulated control. Chronic stimulus parameters were set to evoke minute volumes sufficient for supporting at least 120 percent of basal metabolism based on previous studies of acute intramuscular activation of the phrenic nerve. Injurious effects were avoided by following guidelines established in studies of tissue damage from chronic intramuscular stimulation, and chronic phrenic nerve activation. Performance of the system in all six animals was monitored by periodic function tests during which every implanted electrode was evaluated in terms of the tidal volume and transdiaphragmatic pressure evoked at different stimulus intensities and pulse rates. In the terminal experiment, each dog was killed with an overdose of sodium pentobarbital, and a detailed morphological and histological study of the implanted electrodes and diaphragm was performed.

Results—Intramuscular electrical activation of the phrenic nerve appears to be a safe and reliable means of providing long-term, full-time functional activation of the diaphragm. The performance of the system in all six dogs was stable and remained capable of providing ventilation near or above initial levels throughout the study period. Of 32 electrodes implanted (including 10 used for chronic stimulation), no breakage of the electrode lead occurred and only one stimulating tip dislodged post-operatively. Encapsulation of the electrode appears to prevent electrode dislocation and may enhance the stability of electrode performance. No evidence of cardiac dysrhythmia induced by long-term IDS was observed, and tests for cardiac activation using maximal stimulus pulses (25 mA, 100 microseconds) were negative for all 32 electrodes in every trial performed. The physiology and muscle histochemistry of all chronically-stimulated diaphragms was consistent with previous experience in electrically-stimulated skeletal muscle, where longer muscle twitch times and a predominance of Type I fibers were observed along with an increase in fatigue resistance. Preliminary analysis of tissue around implanted IDS electrodes used for chronic stimulation shows no evidence of damage beyond the encapsulation induced by a mild foreign body response. Finally, scanning electron microscopic examination of explanted IDS electrode tips used for chronic stimulation showed no evidence of pitting corrosion or mechanical failure which would preclude their continued use.

Evaluation of Functional Electrical Stimulation (FES) Techniques for Exercise

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Purpose—The overall goal of this research is to objectively evaluate the effectiveness of functional electrical stimulation (FES) exercise techniques for improving health, physical fitness, and rehabilitation potential of patients with spinal cord injury (SCI). Specific objectives are: 1) assessment of acute physiologic responses and maximal performance during FES leg cycle ergometer exercise (ERGYS), FES knee extension (KE) exercise, voluntary arm-crank ergometer exercise (ACE), and combined ERGYS + ACE (HYBRID) exercise; 2) determination of physiologic response changes resulting from FES exercise training; and, 3) evaluation of psychological adaptations that occur during participation in FES exercise programs.

Progress—For initial implementation, several FES exercise testing protocols were devised to assess strength, endurance, and physical work capacity utilizing each mode of exercise. New KE exercise chairs and multichannel electrical stimulators were designed and constructed to facilitate well-controlled KE weight-lifting exercise. Currently, 40 SCI subjects are participating in FES exercise testing and training. After preliminary medical/physiological evaluation and screening, fitness and functional tests are conducted. These tests consist of lower-extremity strength and endurance assessment (with KE), spasticity assessment (with a Kin-Com isokinetic dynamometer), anaerobic power testing (with ACE), and metabolic/cardiopulmonary responses to graded submaximal and maximal ACE, ERGYS, and HYBRID exercise (utilizing open-circuit spirometry, impedance cardiography, and arterialized capillary blood sampling).

Preliminary Results—To date, we have compared maximal acute physiologic responses of 20 quadriplegics and paraplegics during ERGYS, ACE, and HYBRID exercise testing. For all subjects, mean maximal ERGYS power output (PO) averaged 12.8 W, with an oxygen uptake ($\dot{V}O_2$) of 0.88 L/min, cardiac output ($\dot{Q}$) of 8.8 L/min, heart rate (HR) of 84 beats per minute (bpm), pulmonary ventilation ($\dot{V}E$) of 32 L/min, and blood lactate concentration (HLA) of 5.4 mM/L. HYBRID (ERGYS + ACE) exercise generated the highest mean peak metabolic and cardiopulmonary responses in both groups compared with either exercise mode alone. For example, when comparing quadriplegics with paraplegics, respectively, average total PO was 33 versus 78 W; $\dot{V}O_2$ was 1.13 versus 1.70 L/min; $\dot{Q}$ was 8.6 versus 12.7 L/min; HR was 128 versus 178 bpm; $\dot{V}E$ was 41 versus 75 L/min; HLA was 5.2 versus 5.6 mM/L. This HYBRID exercise appears to evoke metabolic and cardiopulmonary responses of sufficient magnitude and duration to elicit better training responses than either mode of exercise performed separately. Initial KE exercise indicated that quadriceps muscle strength was sufficient to lift an average of 4.7 kg (range: 0.5-15.0 kg) through the 60 degree range of motion for five repetitions.

Future Plans/Implications—Following preliminary subject testing, subjects will train for 12-week periods (3 sessions/week) using either the KE exercise, ERGYS, ACE, or HYBRID exercise modes.

Medical, physiological, and fitness testing will be repeated after each 12-week training period to determine changes in responses. The KE training group will progress to ERGYS training, while the ERGYS group will advance to serial ACE and ERGYS training, performed separately. These groups will then train with HYBRID exercise in an attempt to maximize cardiopulmonary fitness. Analysis of endocrine and substrate responses during exercise testing are also planned. Subsequent progress reports will summarize longitudinal training responses of SCI subjects. We hypothesize that maximizing the active muscle mass through HYBRID arm and leg exercise will provide the metabolic and cardiopulmonary stimulus necessary to elicit significant physiological training responses in the SCI population. This training regime may ultimately play an important role in maintaining long-term fitness while reducing the incidence of medical complications in these active individuals.

Publications Resulting from This Research

Hemodynamic Responses of Quadriplegics to Maximal Arm-Cranking and FNS Leg Cycling Exercise. Figoni SF, Glaser RM, Hendershot DM, Gupta SC, Suryaprasad AG, Rodgers MM, Ezenwa BN. *Proceedings of the 10th Annual Conference of IEEE/EMBS* (in press).

Physiologic Responses of SCI Subjects to Electrically-Induced Leg Cycle Ergometry. Glaser RM, Figoni SF, Collins SR, Rodgers MM, Suryaprasad AG, Gupta SC, Mathews T, *Proceedings of the 10th Annual Conference of IEEE/EMBS* (in press).

Automated Autonomic Nervous System Function Analysis System. Ezenwa BN, Figoni SF, Glaser RM, Ponichtera JA, Almeyda JW, *Proceedings of the 10th Annual Conference of IEEE/EMBS* (in press).

Sacral Nerve Stimulation for Neurogenic Bladder Management in Spinal Dog

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Sponsor: *Rehabilitation Research and Development Center, Edward Hines, Jr. VA Hospital*

Purpose—This project's goal is to learn more about the mechanism of bladder dysfunction following spinal trauma, and to use this knowledge to develop ways to enhance bladder function following injury. In particular, we have evaluated minimally-invasive methods of stimulating sacral nerves to induce bladder contractions and manage the neurogenic bladder. These observations complement studies focusing on clinical trials for bladder management following spinal cord injury (SCI).

Progress—Eight spinal dogs (T8-9) were instrumented with a 6-electrode array of epidural electrodes (Pisces Quad and Sigma, Medtronic) implanted adjacent to sacral nerves using a modified percutaneous procedure. These spinal animals were urologically managed for 8 weeks with intermittent catheterization or sacral stimulation using either the epidural electrodes or sacral surface electrodes.

For the first 3 weeks postspinal, voiding was often very poor with only 0-20 ml collected after each 1- to 3-second sacral stimulation period. Often the bladder was ineffectively emptied, leaving high residual volume and requiring catheterization to drain the bladder. By week 4, stimulation induced effective voiding of 10 to 100 ml, and residual urine was less than 50 ml, after a series of 4-6 stimulations repeated 1-3 times. To study this improved voiding during the first 3 weeks, 3 of 8 spinal animals were intermittently catheterized during the first 4 weeks, followed by sacral stimulation for voiding. Stimulation on week 5 induced effective voiding, demonstrating that early stimulation was not necessary for the recovery of bladder activity.

Results—Optimum stimulating parameters for inducing bladder contractions have been determined. For implanted electrodes, at the low stimulating current of 1 mA, lateral electrodes adjacent to the sacral nerves were most effective. At 5 mA, a single monopolar electrode on the sacral midline was as effective as the lateral electrodes for stimulating sacral nerves. For daily voiding we used repeated stimulation with 2.5 mA, 10 pps, 0.3 ms pulse duration applied for 2 to 3 sec. For surface electrodes, placement directly over sacral foramina was optimal. Stimulating currents and optimum pulse durations were higher than for implanted electrodes, from 35 to 45 mA and 0.6 ms pulse duration, whereas other stimulating parameters were similar to implanted electrodes.

Voiding was accomplished in the spinal dog at low bladder pressure, and the voiding pattern was usually pulsatile. Electromyographic recordings from the pelvic floor showed phasic discharges, and fluoroscopic observations showed opening and closing of the membranous urethra resulting in the phasic flow pattern. These observations indicate that the spinal dog may not be a good model for the high pressure voiding problems seen in SCI patients.

Publications Resulting from This Research

Surface Electrical Stimulation to Induce Micturition in the Spinal Dog. Walter JS, Wheeler JS, Stein J, Bolam J, Robinson CJ, *J Urol* 137:107A, 1987.

Urethral and Pelvic Floor Function in the Chronic Spinal Dog. Walter JS, Wheeler JS, Robinson CJ, Wurster RD, *Society for Neuroscience* 13:204.4, 1987.

Urodynamic Responses to Sacral Stimulation in the Chronic Spinal Dog. Walter JS, Wheeler JS, Robinson CJ, Bolam J, Wurster RD, *Neurourol Urodynam* 7:13-25, 1988.

A Trial of Chronic Electrical Stimulation in Early Duchenne Muscular Dystrophy

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The aim of this study is to test the hypothesis that chronic electrical stimulation increases strength and endurance in the early phase of Duchenne muscular dystrophy.

Progress—We propose to test a large proximal muscle, the quadriceps femoris, over a period of 12 months in 10 boys aged 3 to 9 years. Stimulators have been obtained from Neen Pain Management Systems, UK. A system for measuring strength and endurance, consisting of a positioning chair, force transducer, amplifier, display and plotter, is being assembled.

Future Plans/Implications—Our results should help define whether chronic electrical stimulation should become a part of the therapeutic armamentarium in the management of Duchenne dystrophy by delaying the progressive weakness characteristic of the condition.

Optimization of a Spinal Cord Electrode

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purposes of this project are to: 1) develop a stimulation probe that will select certain cord systems in the spinal marrow that can be stimulated; 2) obtain insight into the effects of using different electrode positions and different anode-cathode combinations; and, 3) test the stimulation probe with patients with partial spinal cord lesions.

Progress—A 3-dimensional computer model of the spinal marrow and the surrounding tissues was constructed on which potential distributions within the spinal marrow could be measured. In order to test the reliability of the model, research into the parameter sensibility of the electric conductivity of the various tissues has been started.

This project is being conducted in cooperation with the Neurosurgical Centre Twente, Enschede, and the Rehabilitation Centre Het Roessingh, Enschede.

Rehabilitation Engineering Center for Restoration of Neural Control

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Program Overview

Purpose—The objectives of the Rehabilitation Engineering Center for Functional Electrical Stimulation at Case Western Reserve University (CWRU-REC) are to: 1) develop, test, implement, and evaluate clinical systems employing functional electrical stimulation (FES) technology which provide control of the extremities, stabilization of the trunk, and function of the respiratory and urinary systems; 2) provide implementers, providers, and users with current information about FES; 3) deploy FES systems to other rehabilitation and research institutions; and, 4) transfer FES technology to private industry.

FES can be used in several ways to effect control of the nervous system. FES can control abnormal motor system function resulting from stroke, head injury, cerebral palsy, or scoliosis. It can also restore motor and sensory function loss due to paralysis resulting from spinal cord injury or stroke. In this program, we will address the problems presented by individuals with these injuries.

The program is organized to promote investigation in seven priority areas: 1) development of a comprehensive FES information base; 2) upper extremity FES and hybrid systems for manipulation and grasp; 3) systems employing FES and orthotics to stabilize the trunk and correct trunk deformities; 4) control of spasticity in stroke and head injury by FES; 5) control of respiration in central respiratory insufficiency; and, 6) control of micturition in the neurogenic bladder by FES.

The first project is one of information collation and dissemination, and is discussed in detail below. The remaining projects involve clinical implementation to restore functional control, and are presented on the following pages.

Information Dissemination on FES

Geoffrey B. Thrope, BS

Purpose—We will provide means for disseminating information on FES to handicapped individuals, service providers, industry, clinicians, and researchers in a form that is easily accessible and meets regional and national needs. Two primary means for dissemination of information have been incorporated into the Center program. They are: 1) the development of an Information Center; and, 2) the professional activities of each of the investigators.

The Information Center will be operated by the Services for Independent Living program, in conjunction with the CWRU-REC, and will collect and distribute information to parties inquiring about FES. Information exchange in a technologically complex and rapidly-evolving area such as FES requires that several types of data be made available. The first type is aimed at the consumer of FES technology, who must be provided with information regarding products and deployers of the technology. The second is for clinical implementers (physicians, therapists, and rehabilitation engineers) whose interests are similar, but generally at a more technical level. The third, information regarding system hardware and procedures, will be made available to researchers in the field. The fourth, to be circulated among professionals, is published research results from the peer-reviewed literature, abstracts from meetings, and progress reports. Through the activities carried out in this project, we will assemble such information and make it available to interested parties.

Dissemination of information will also be the responsibility of individual researchers, who will publish results in professional journals and texts, organize and participate in meetings and workshops, and interact with interested service providers and consumer groups for the disabled. A major effort has been directed at providing information and service to each of these sectors.

Development of Upper Extremity Control Employing Functional Electrical Stimulation

P. Hunter Peckham, PhD; Michael W. Keith, MD

Purpose—The objective of this project is to clinically evaluate the efficacy of FES systems which provide restoration of grasp and release for the high level quadriplegic user. The first systems to be evaluated has been developed in this Center to enable individuals with spinal cord injury at the C5 and C6 level to regain control of two prehension patterns, palmar and lateral prehension, through chronically-indwelling percutaneous electrodes. Building on an already existing preliminary effort with centers in Edmonton, Alberta, and Toronto, Ontario, we will transfer this technology to four Centers in addition to our own and perform carefully regulated and supervised trials to validate the findings in our own research.

Electrical Stimulation in the Treatment of Scoliosis

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Purpose—We will test in human subjects, a method of correcting scoliosis that utilizes electrical activation of deep paraspinal muscles on the concave side. Previous studies have shown that the deep paraspinal muscles of the concave side are longer and less active than those on the convex side, suggesting that if they are activated, correction of spinal curvature would follow. Further, our previous studies have shown that the muscle activity is highest on the convex side during the time the patient is awake and moving about, and the least when the patient is resting or asleep, suggesting that electrically-induced contractions might be more effective if applied during the waking hours rather than the sleeping hours.

Methodology—Helically-wound wire electrodes will be inserted into the deep paraspinal muscles on the concave side of the curve of adolescent patients with scoliosis. The patients will be in one of three groups: one group receiving stimulation during the daytime period, another during the nighttime period, and the third receiving stimulation during both periods. Most patients participating in the study will have stimulation applied for two years, and then they will be followed closely for at least one year after cessation of the electrically-induced muscle contractions. The initial study will be a pilot study involving 5 to 10 patients in each group and will take place during the first three years. During the fourth and fifth years a large scale study will be undertaken using the information gained during the first three years to design that study.

Characterization and Reduction of Spasticity by Stimulation in the Hemiplegic Upper Extremity

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Purpose—The goal of this study is to improve upper extremity function in patients with hemiplegia by reducing spasticity and improving voluntary control by electrical stimulation. Electrical stimulation of finger and thumb extensor muscles of the ulnar nerve is expected to reduce resting activity levels in spastic muscles and to increase voluntary control. The effects of stimulation will be quantified by measurement of the electromyographic activity in the stimulated muscles, and in muscles representing the major flexor and extensor groups of the fingers, the thumb, and the elbow. Effects of stimulation will also be quantified by measuring the kinematics of voluntary and stimulus-induced movements at the fingers, thumb, wrist, and elbow.

Quantification of spasticity by measurement of the increased resistance to joint rotation (stiffness) is frequently complicated by changes in initial conditions. If this dependence can be quantified and if it is repeatable, then spasticity and therapeutic methods may be measured more easily. The dependence of stiffness on the initial activation levels of co-contracting antagonists will be measured both in normals and in subjects with spasticity. A technique will be used that enables the separation of mechanical and reflex components of the stiffness. This technique will also be used to further characterize the effects of stimulation on the reflex sensitivity to stretch and allow future improvement of methods of reducing spasticity.

Treatment of Respiratory Insufficiency Using Intramuscular Stimulation of the Diaphragm

J. Thomas Mortimer, PhD; Michael Nochomovitz, MD; Thomas Stellato, MD

Purpose—This project is aimed at performing the first clinical trials of an intramuscular diaphragm stimulation system on human patients suffering from chronic ventilatory insufficiency. This system uses electrodes placed directly into the diaphragm under observation by a laparoscope and does not require any form of physical contact with the phrenic nerve. This technique would make diaphragm pacing available to a much larger group of patients who would otherwise not undergo the risks and costs of diaphragm pacing with the conventional phrenic nerve stimulation system. A detailed description of the procedures for patient selection, electrode implantation, and system evaluation are given along with a risk analysis for the intramuscular diaphragm pacing system. The goals of this investigation are to use technology from previous research in an animal model to perform clinical trials and to disseminate the results from these trials to the rehabilitation community.

Micturition Assist System for Spinal Cord Injured Patients

James D. Sweeney, PhD; Donald Bodner, MD

Purpose—The objective of this study is to develop and test a micturition assist system for the spinal cord injury patient with hyper-reflexic bladder paralysis and detrusor/external urethral sphincter dyssynergia. The device will be based on the technique of "collision block" of pudendal nerve activity for relaxation of the external urethral sphincter muscle and, if necessary, "sacral root stimulation," for activation of detrusor contraction.

Sacral root stimulation has been shown to be a feasible method of effecting bladder pressures sufficient for voiding. Unfortunately, the electrically-induced bladder contraction is accompanied by a concomitant contraction of the external urethral sphincter in spinal cord injury patients with an intact sacral spinal cord. Co-contraction of the sphincter and bladder results in poor urine flow and incomplete voiding. Relaxation of the external urethral sphincter through reversible collision block of its somatic motor neuron input could eliminate this problem. Development of such a collision block system is currently underway with other funding. This animal testing of collision block effectiveness and safety will be concluded by 1990.

We propose to at that time implant the collision block electrode system into spinal cord injury patients with hyper-reflexic bladder paralysis, and to evaluate the response of the patient to collision block of the pudendal nerve. If the voiding response of the patient can be improved by adding sacral root stimulation, we will implant sacral root electrodes in the same patients and evaluate their response to combined sacral root stimulation and collision block stimulation.

Recruitment Characteristics of Implanted Electrodes

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Recruitment data for nerve cuff and epimysial electrodes were needed to establish specifications for the range and resolution of pulse amplitude and duration for implantable stimulators. In this study, these data were collected from electrodes chronically implanted in cats.

Progress—Three configurations of cuff electrodes were considered: monopolar, bipolar, and tripolar. About twice as much charge per pulse was required to achieve a given response with the tripolar configuration when compared with the monopolar configuration. The bipolar configuration was intermediate to the other two with respect to charge requirements.

Epimysial electrodes required much higher currents than the cuff configurations. About 30 to 50 times as much charge was required to achieve the same response using epimysial electrodes as compared with monopolar stimulation.

Results—Using the recruitment data for the nerve cuff electrodes, an analysis was made of two modulation schemes for controlling muscle activity: pulse amplitude modulation (PAM), and pulse duration modulation (PDM). For PAM, it is desirable to operate at a low pulse duration and in the high end of the allowable range for pulse amplitude. For PDM, one should select a low pulse amplitude and operate in the high end of the allowable range for pulse duration.

Publications Resulting from This Research

Recruitment Data for Nerve Cuff and Epimysial Electrodes. McNeal DR, Baker LL, Symons J, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:651-653, 1987.

Recruitment Characteristics of Nerve Cuff Electrodes and Their Implications for Stimulator Design. McNeal DR, Baker LL, Symons J, *Proceedings of the 9th International Symposium on External Control of Human Extremities*, Dubrovnik, Yugoslavia, 15-25, 1987.

Percutaneous Epimysial Electrodes

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Purpose—Electrical stimulation has been shown to be an effective tool to activate skeletal muscle in patients with weakness due to immobilization or upper motor neuron disorder. Surface electrodes have not proven to be satisfactory, however, when the muscles to be stimulated are deep to other structures or are located adjacent to antagonistic muscles.

Progress—In this clinical study, epimysial electrodes were surgically placed on key lower limb muscles for the purpose of augmenting hip and knee control. Six patients with hip and/or knee weakness were selected from the stroke, head trauma and spinal injury clinics at Rancho Los Amigos Medical Center. Routine clinical evaluation was augmented with electrodiagnostic studies and kinesiological electromyography. The gluteus medius, gluteus maximus, and adductor magnus muscles were selected to enhance hip stability in stance, and the quadriceps muscle was stimulated to improve knee extension. The short head of the biceps femoris was employed to gain knee flexion and the iliacus and sartorius were used to increase hip flexion. Titanium electrodes, approximately 4 mm in diameter with a silastic backing, were sutured to the epimysium after intraoperative verification of the optimal stimulation site. Insulated stainless steel leads were directed subcutaneously to exit the skin in a common site. The leads were enclosed in a connector for communication with a commercially-available stimulator.

Results—Electrically-stimulated and voluntary moments improved over a stimulation period of 3 to 6 months. Surface stimulation produced minimal contractions when compared to epimysial activation of the deep hip muscles. The problem of undesirable activation of the quadriceps during sartorius stimulation via epimysial electrodes awaits solution. Impedance and threshold values, within an individual subject, remained stable. Clinical outcome, although not attributable to electrical stimulation alone, has been promising. Four of the six patients have become ambulatory after periods of 3 months to 10 years in a wheelchair, and ease of mobility has improved in all patients.

Implications—These preliminary results demonstrate the feasibility of obtaining selective, functional contractions of deep muscles with epimysial electrodes. The future patient who does not gain adequate volitional control during this short-term application of stimulation would benefit from conversion of the percutaneous to an implanted system.

Publications Resulting from This Research

Therapeutic Electrical Stimulation of the Lower Limb by Epimysial Electrodes. Waters RL, Campbell JM, Nakai R, *Clin Orthop Rel Res* 233:44-52, 1988.

Epimysial Electrical Stimulation: Short-Term Therapeutic Applications. Campbell J, Nakai RJ, Waters RL, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:657-659, 1987.

Preliminary Results of the Therapeutic Electrical Stimulation Utilizing Epimysial Electrodes. Waters RL, Campbell J, Nakai R, *Proceedings of the 9th International Symposium on External Control of Human Extremities*, Dubrovnik, Yugoslavia, 65-69, 1987.

Preliminary Characterization of Epimysial Electrodes Used to Electrically Activate the Paralyzed Lower Extremities. Nakai RJ, Campbell J, McNeal DR, Waters RL, *Proceedings of the 9th Annual IEEE-EMBS Conference*, Boston, MA, 1565-1566, 1987.

Muscle Stimulation for Spinal Deformities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Idiopathic scoliosis is a common spinal deformity which, if left untreated, can produce cosmetic deformities, back pain, degenerative joint disease of the spine, and impaired cardiopulmonary function. An orthosis, such as the Milwaukee or Boston brace, is generally prescribed in the early stage of the disease. If progression of the curve is not controlled with a brace, surgical correction of the deformity is generally required. The purpose of this research was to study the lateral electrical surface stimulation (LESS) of the trunk muscles, which has been shown to be an effective alternative to bracing. The major advantage of LESS is that it is used only at night, and the patients are not required to wear a brace or any other equipment during the day.

Progress/Preliminary Results—As a result of re-

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search initiated at our Center in 1976, a device called the ScoliTron has been developed in collaboration with Neuromedics, Inc. A multicenter study involving 548 patients and 54 principal investigators in North America and Western Europe was completed during this grant period. It was concluded that LESS stabilizes actively progressing juvenile or adolescent scoliosis at least until spinal maturity. The study population is being followed and will continue to be followed into adulthood to determine long-range effectiveness.

The Effect of Electrical Stimulation on Cutaneous Oxygen Supply

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Purpose—Certain patient populations are known to have difficulty in healing ulcerations of the skin. Two of these groups are patients with diabetes and the spinal cord injured patient. Electrical stimulation has long been used clinically to enhance the wound healing process. Very little, however, has been published as to its clinical efficacy, and virtually nothing has been reported attempting to assess the mechanism by which stimulation may enhance wound healing. In an effort to identify what type of stimulation may be most efficient in causing an increased rate of wound healing, assessment of the mechanism by which electrical stimulation effects the healing process is necessary. One mechanism by which stimulation may have its effect is through the enrichment of oxygen and other nutrients to the affected area. The use of a transcutaneous oxygen-sensing electrode has provided the means to assess this particular aspect of electrical stimulation, as used to enhance wound healing.

Progress—Thirty diabetic subjects have been tested with a variety of electrical stimulus waveforms to determine their transcutaneous oxygen (tc-PO_2) response to the stimulation. In addition, 20 age-matched normal subjects have also been tested. Testing of 40 patients with spinal cord injury is ongoing at the present time. After establishing a tc-PO_2 baseline, each subject or patient received 30 minutes of electrical stimulation, followed by a second 30-minute period of no stimulation. The following electrical stimulus waveforms have been tested: monophasic paired spikes, using both positive and negative polarity in the test area; compensated monophasic square waveform, both just below the motor threshold, or creating a Trace level muscle contraction; symmetrical biphasic square waveform.

Preliminary Results—In the diabetic subjects, a measurable increase in tc-PO_2 was present at the end of the 30-minute stimulation, and tc-PO_2 values continued to rise during the ensuing 30 minutes of no treatment. This pattern was seen regardless of the waveform used. No waveform demonstrated greater or earlier increases in tc-PO_2. Stimulation at Trace muscle contraction did, however, seem to blunt the tc PO_2 response in the diabetic subjects. The age-matched normal subjects demonstrated the same type of change in tc-PO_2, but usually presented with the increased oxygen levels earlier in the treatment period, significant changes often being recorded at 15 minutes. Diabetic subjects began the baseline period with significantly lower tc-PO_2 levels than their age-matched normal counterparts, indicating that part of the difficulty for the diabetic patient in healing wounds may be lack of adequate oxygen and other nutrients. Thus the increase in tc-PO_2 accompanying the use of sub-motor electrical stimulation may enhance the diabetic patients' ability to heal superficial ulcers. Further assessment of what features in the electrical stimulus enhance this process is needed.

Publications Resulting from This Research

The Effects of Electrical Stimulation on Cutaneous Oxygen Supply in Diabetic Older Adults. Dodgen PW, Johnson BW, Baker LL, Chambers RB, *Phys Ther* 67(5):793, 1987.

Factors Affecting Comfort During Cutaneous Stimulation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Clinical use of NeuroMuscular Electrical Stimulation (NMES) has dramatically increased during the last several years. A continued impediment to the practical use of NMES with some patients is the cutaneous sensation elicited by the electrical currents. Identification of stimulus parameters that minimize the discomfort of NMES will greatly enhance this valuable treatment's usefulness in the rehabilitation of both neurologic and orthopedic patients.

Progress—Over the past several years a paradigm has been developed which provides reproducible information regarding subject preference for different stimulus parameters. Most recently, an additional component of the paradigm has been added, which provides for an assessment of the degree of preference by subjects. Stimulus parameters which have been studied using the complete protocol include: stimulus frequency (30, 50, and 100 pps); stimulus waveform (symmetrical biphasic square, compensated monophasic square, monophasic paired spikes, medium frequency square, and medium frequency sine wave). In addition, three commercially available electrodes have been tested with the protocol. Several comparisons were done without the degree of preference component of the protocol. Parameters studied under these conditions include: pulse duration (12, 50, 100, 300 and 800 μsec); waveform (symmetrical biphasic square, compensated monophasic square, monophasic paired spikes, and medium frequency sine); generator source (constant current and constant voltage).

Results—Results from these studies indicate that a mid-range pulse duration, a relatively high frequency, and for large muscles, a symmetrical biphasic square waveform are perceived as most comfortable. The generator source has not been found to be particularly critical in determining subject comfort. Medium frequency waveforms have not been found to be more desirable than the symmetrical biphasic pulse in any comparison to date. These data have been made available to manufacturers who design stimulators, and in some cases have been incorporated into new equipment commercially available to the practicing clinician.

Publications Resulting from This Research

Comparison of Three Waveforms for Comfort During Electrical Stimulation. Baker LL, Borup C, Mann M. *Phys Ther* 67(5):793, 1987.

Effect of Duty Cycle on Muscle Fatigue

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—A study done at this Center has identified that most subjects prefer a higher frequency for comfort during NeuroMuscular Electrical Stimulation (NMES). This was found to be universally true in naive subjects, those who had minimal exposure to NMES prior to the study. Subject comfort is a major concern during NMES treatments, especially as it relates to the initial perception of NMES at the initiation of a treatment program. Use of stimuli that are less than optimal may require the therapist to use an extended training program, acclimating the patient to the unusual sensory experience which accompanies NMES. A problem arises in using high frequency NMES, since stimulated contractions tend to be very fatiguing to the muscle. Thus, if a higher frequency of NMES is to be used for comfort, modified duty cycles must be determined to minimize the fatigue effect and allow an adequate treatment time.

Results—Several studies have been undertaken to evaluate the effects of different duty cycles when various stimulus frequencies are used. To date, stimulus frequencies and the duty cycles evaluated include: 100 pulses per second (pps) at 1:3, 1:5, 1:7 and 1:10; 50 pps at 1:3, 1:5, 1:7 and 1:10; 30 pps at 1:1, 1:2, 1:3, 1:5 and 1:7. In addition, the effect of a 1:3 duty cycle using 30 pps with variable ON times is in the process of being evaluated.

The duty cycle which provided the greatest amount of contraction time with an acceptable level of fatigue was different for each of the tested frequencies. When the frequency of 100 pps was used, the only acceptable duty cycle was the 1:10 ratio. All other duty cycles demonstrated marked fatigue very early in the 30-minute assessment period. When the frequency of 50 pps was used, the duty cycle of 1:7 was found to be acceptable to avoid muscle fatigue, and provided for more actual contraction time in the 30-minute assessment period than did the 1:10 duty cycle. In clinical terms, this would translate into more actual treatment for the patient during each 30-minute NMES session. Using the frequency of 30 pps, the duty cycles of 1:2 and 1:3 were found to be adequate to avoid major problems in muscle fatigue during the 30-minute assessment period. Because of the decreased amount of contraction time achieved during a 30-minute treatment session, recommendations to clinicians include the use of a higher frequency (50 or 100 pps) with the appropriate duty cycle during the training period, providing the patient with an optimally comfortable stimulation. After adequate tolerance has been achieved by the patient, a move back to a frequency of tetany (30 pps) with the use of an appropriate duty cycle would allow the therapist to increase the actual amount of treatment given during any session.

Publications Resulting from This Research

Muscle Fatigue During Electrically Induced Isometric Contractions at Varying Duty Cycles. Cole KF, Sledge MM, Baker LL, McNeal DR, *Phys Ther* 67(5):792, 1987.

Implant Device Development

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Sponsor: *National Institutes of Health*

Purpose—The purpose of this project is to study the interaction between biomaterials and the physiological environment and to determine the suitability of specially-prepared biomaterials for use in various contexts. Polymers, metals, and ceramics are important for use in catheters, heart-assist pumps, electrode insulation, and similar implant applications. Variations in these materials, as well as physically-induced stress and environmentally-accelerated degradation, can severely reduce their effectiveness for long-term use as surgical devices.

Previous studies undertaken by this project have shown a relationship between the molecular chain structure and resistance to hydrolysis. Recent evidence suggests that physical forces such as stress induced during fabrication can promote a form of stress corrosion. *In vitro* test data and SEM photomicrographs of surgical explants of various polyurethane classes show that premature failure is often the result of a combination of forces acting on the polymer at stress risers. Polymer systems and composites capable of time dissolution offer significant advantages in the development of devices that allow natural tissues to take over as healing.

Non-Invasive Stimulation of the Human Central Nervous System

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Sponsor: *National Institutes of Health*

Purpose—Recently, techniques have become available for the non-invasive stimulation of the human cortex and human spinal cord. A device has been manufactured which produces a high-voltage, extremely brief pulse which can penetrate the skull and activate the central nervous system without excessive pain. Previous studies have shown it to be useful in some circumstances where evaluation of the speed and integrity of motor pathways is valuable.

Results—Our project to map the motor cortex has demonstrated that it is possible to identify discrete areas for the leg, hand, upper arm, and face. Studies with somatosensory-evoked potentials have shown that the motor areas are discrete from, and anterior to, the primary sensory areas as revealed by the topography of the early components.

Neural Tissue Microchip Interface

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Sponsor: *National Institutes of Health*

Purpose—The development of a neural prosthesis requires the fabrication of a solid-state device capable of recording information from neural tissue and stimulating it in a timely manner.

Progress—We began this process by designing a simpler system to test and monitor cultured neural tissue. To date, we have identified problems such as suitable insulation for the device and some problems with corrosion in a critical part of the system. In addition, we have improved the tissue culture system in an attempt to make the tests as realistic as possible. We have also worked with cultured retinal tissue in the system so that two-way communication could be achieved.

The Use of EMG as Force Feedback in Closed-Loop Electrical Stimulation System

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Sponsor: *National Science Foundation*

Purpose—Force feedback is necessary if regulation of a stimulated muscle force output is anticipated. Since implantation of a force sensor requires traumatization of the tendon, an electromyogram (EMG) was considered, tested, and evaluated as a parameter representing force in a closed-loop paradigm.

Results—The full wave rectified and low pass filtered EMG was shown to follow the force trace rather faithfully as long as fatigue did not set in the muscle. The above simple processing of the EMG was superior to its root-mean-square (RMS) mean frequency processing. Furthermore, a set of EMG-force relationships of a stimulated fast and slow twitch muscles under various firing rate and recruitment control strategies was developed and optimized in a closed-ioop configuration.

Current work focuses on assessment of the effect of dynamic (non-isometric) factors on the EMG-force relationships.

Publications Resulting from This Research

The EMG-Force Model of Electrically Stimulated Muscle: Dependence on Control Strategy and Predominant Fiber Composition. Solomonow M, Baratta R, Zhou BH, Shoji H, D'Ambrosia RD. *IEEE Trans Biomed Eng* 34:692-703, 1987.

Development of a High Performance Electrical Stimulation System for the Rehabilitation of Paralyzed Muscles and the Study of Muscle Properties

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Purpose—A computer-controlled stimulation system was developed with the objective of eliciting force with separate and simultaneous control of action potentials firing rate and motor units recruitment according to their size. The system used dual bipolar cuff electrodes placed on the muscle nerve, with firing rate stimulus applied to one electrode, and orderly recruitment of axons according to their diameter applied via the second electrode by gradual release of axons from a high frequency block.

Results—The recent development of the system demonstrated its ability to elicit muscle force under various firing rate and recruitment control strategies as observed in voluntary contraction of various skeletal muscles. The superiority of the system was assessed by virtue of the smoothness of the force developed, its high resolution, resistance to fatigue, and linearity of the input-output of the system.

Additional developments undertaken last year resulted in the validation of the orderly recruitment of motor units according to their size and the reduction of the two bipolar electrodes into a single tripolar electrode while maintaining the same performance.

Publications Resulting from This Research

Manipulation of Muscle Force with Various Firing Rates and Recruitment Control Strategies. Zhou B, Baratta R, Solomonow M, *IEEE Trans Biomed Eng* 34:128-139, 1987.

The EMG-Force Model of Electrically Stimulated Muscle: Dependence on Control Strategy and Predominant Fiber Composition. Solomonow M, Baratta R, Zhou BH, Shoji H, D'Ambrosia RD, *IEEE Trans Biomed Eng* 34:692-703, 1987.

Control of Joint Motion with FES of the Antagonistic Muscle Pair

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Sponsor: *National Science Foundation*

Purpose—Restoring fine control of movement to a paralyzed extremity joint is difficult if the joint's stiffness is not regulated. In voluntary conditions it is done by the antagonist muscle, eluding to the use of FES for the antagonist stimulation concurrently with power generation in the agonist. This study was undertaken to identify the fundamental modes and control strategies employed by the antagonist under various loading conditions in the regulation of the joint's stiffness.

Results—It was found that the antagonist plays a major role in the control of movement: 1) it increases its activity level as the agonist force is increasing; 2) it regulates the joint torque against the effect of the gravity vector; 3) it regulates joint stiffness as a function of the limb's velocity; 4) it stabilizes the joint, regulates articular surface pressure and protects the ligaments from overloading; 5) it provides constant, low level, opposing torque to the intended movement; and, 6) it regulates the movement in the face of various external and internal disturbances.

Preliminary Results—The data documented so far points out that potential damage to the joint and its associated tissues may be inflicted in FES systems that do not stimulate the antagonist concurrently with the agonist.

Publications Resulting from This Research

The Synergistic Action of the ACL and Thigh Muscles in Maintaining Joint Stability. Solomonow M, Baratta R, Zhou B, Shoji H, Bose W, Beck C, D'Ambrosia R. *Am J Sports Med* 15:207-213, 1987.

Muscular Coactivation. Baratta R, Solomonow M, Zhou B, Letson D, Chuinard R, D'Ambrosia R, *Am J Sports Med* 16:113-122, 1988.

EMG Coactivation Patterns of the Elbow Antagonist. Solomonow M, Baratta R, Zhou B, D'Ambrosia R, *Exp Neurol* 100:470-477, 1988.

Psychosocial Aspects of Functional Electrical Stimulation

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Sponsor: *Rehabilitation Institute of Chicago; National Institute on Disability and Rehabilitation Research*

Purpose—This report describes one component of the Rehabilitation Research and Training Center for the Prevention and Treatment of Secondary Complications of Spinal Cord Injury awarded to Northwestern University and the Rehabilitation Institute of Chicago by the National Institute on Disability and Rehabilitation Research.

Rehabilitation for persons who are paraplegic due to traumatic spinal cord injury (SCI) typically emphasizes development of residual skills and adjustment to diminished body functioning. The development of technology to achieve stance and ambulation with functional electrical stimulation (FES) may significantly alter rehabilitation objectives and practice. Achievement of greater functional autonomy with FES for some persons who are paraplegic is the goal of several research groups. FES was first used to achieve stance in 1960. Today, ambulation with external support has been achieved with a limited number of persons in specially designed laboratories; the Rehabilitation Institute of Chicago in collaboration with the Pritzker Institute of Medical Engineering (PIME) at Illinois Institute of Technology (IIT) is one site where research is being conducted to develop a versatile, reliable, and safe system that allows stance and ambulation in community settings. Continued development promises eventual availability to many persons who are paraplegic. Next to a cure for SCI, such an external means of achieving function is a high priority for many persons with SCI.

Such a system can be expected to have a significant impact on the lives of users. The psychological status of both potential users and those unable to acquire this system is likely to be influenced as well. The psychological and social effects on individuals participating in a program in which personal benefits can not be guaranteed, may be critical to research success; however, possible effects have not been investigated. The life adjustment achieved by research participants is likely to be a critical factor. Careful selection of participants based on a thorough review of previous coping skills and an ability to tolerate uncertainty appears warranted.

In summary, the objectives of this project are to: 1) define and evaluate inclusion and exclusion criteria for research participants, particularly psychological and social characteristics associated with successful research involvement; 2) evaluate the short and long effects of FES on participants, while taking into account the full context of their life situations; the effects of research involvement on participants' vocational and psychological adjustment; and, 3) contribute to an understanding of the process of adjustment following severe traumatic injury and the accompanying return of physical functions.

The study will be composed of all persons referred to the Rehabilitation Institute of Chicago-Pritzker Institute of Medical Engineering for FES participation. Approximately 24 persons per year will be recruited.

The Representative Case Method (Shontz, 1965;

Spotts and Shontz, 1980) will be adapted for this investigation. The participants are used as expert consultants because they are in a unique position to report on the effects of and their reactions to the rehabilitative processes under investigation.

Intensive interviews will be used to assess each participant's life history, characteristic coping strategies, health history, rehabilitation, adaptation, attribution of responsibility for injury, and personal consequences of FES research selection anu participation. Demographic data and information regarding family relationships, education, employment, and religion will be collected. All persons who agree to participate will be told the purpose of the research and will be asked to review and comment on interpretations and conclusions.

Fatigue of Paralyzed Muscles Activated by Functional Electrical Stimulation in Paraplegics

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Sponsors: *Technion VPR-Fund; Israel Ministry of Defense; Segal Foundation; Montreal Biomedical Research Fund*

Purpose—The nature of fatigue of paralyzed muscles activated by functional electrical stimulation (FES) is essentially peripheral. Of the two aspects which characterize normal muscle fatigue, the peripheral and the central, the latter is absent in the muscles of the lower limbs of paraplegic patients. A major expression of muscle fatigue under FES is a gradual decay in the force produced.

If the leg of a paraplegic patient is treated as a dynamic system, having forces in the activated muscle only, it may be treated as a determinate system, allowing to noninvasively calculate the internal muscle and joint forces developed. In this study, we have developed a method for the *in vivo* continuous evaluation of the quadriceps muscle and knee joint forces of paraplegics, under FES. Furthermore, measurement of the myoelectric activity in the course of fatigue allows us to correlate together the force and electromyographic (EMG) parameters of the activated quadriceps muscles.

Methodology—The quadriceps muscles of paraplegic patients (with spinal cord injury level between D5-D11) are stimulated externally by monophasic rectangular pulse trains, with parameters ranging as follows: frequency between 18 and 30 Hz, pulse-width between 0.1 and 0.3 ms and intensity up to 200 mA (corresponding to 110 V approximately). During the course of stimulation, the frequency and pulse-width are usually kept constant at 20 Hz and 0.3 ms respectively. Intensity, however, if also kept constant, becomes increasingly insufficient due to muscle fatigue, resulting in a gradual decay in muscle force.

Mechanical measurements are made to determine, by means of a mechanical model, the force occurring in the quadriceps muscles during stimulation in isotonic and isometric activation. These are done by specially-constructed apparatus instrumented for force measurements.

Simultaneously, surface EMG measurements are being made by which the following data are obtained: latency, conduction velocity, and F-wave latency. Additionally, the myoelectric activity of the stimulated muscle is obtained by means of the M-wave, whose parameters, namely peak to peak amplitude and rise time, are measured continuously during activation.

Results—The results obtained provide the forces acting in the quadriceps muscles as well as in the knee joint, in the course of fatigue, during activation by FES. The EMG measurements indicate that latency, F-wave latency, and conduction velocity are not significantly affected as a result of FES. On the other hand, the M-wave parameters obtained are systematically altered in the course of fatigue, resulting in a continuous increase in rise time and a decrease in peak-to-peak amplitude.

Good correlation is found between the force and peak-to-peak EMG decay curves.

Future Plans/Implications—The problem of muscle fatigue of activated paralyzed muscle of paraplegic subjects is being investigated noninvasively from its mechanical and myoelectrical aspects. We have recently started using magnetic resonance imagimg (MRI) techniques to study the metabolic expression of fatigue. It is hoped that the results obtained will enable the phenomenon of fatigue to be expressed more completely, for more effective and better application of FES.

Publications Resulting from This Research

Fatigue of Quadriceps Muscles Continuously Activated by FES in Paraplegics. Levy M, Mizrahi J, Susak Z, Solzi P, *7th Congress of ISEK*, 5, Enschede, Holland, 1988.

An Implantable Sensor for Two-Degree-Freedom Joint Position Transduction

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Development has begun on an implantable joint angle sensor. An implantable sensor is an important part of ongoing development of neural prosthetic devices for the spinal cord injury population. These neural prosthetic devices utilize functional electrical stimulation (FES) of the paralyzed muscles to restore grasp-release function to the hand and forearm in individuals who have spinal cord injury at the C5 or C6 level. Ultimately, key components of these systems must be implantable to minimize the inconvenience of externally-placed components. The implantable joint angle sensor, funded by this project, is one of these key components. The sensor will provide a command source for the users to control their prosthetic system, and will also provide feedback to the system about the movement of the user's arms or legs.

Progress—The work accomplished under this grant includes an analysis of the transduction technique that will be utilized by the sensor and the preliminary design of packaging techniques that will be used to make the sensor implantable. The sensor has two parts, a permanent magnet, and an array of four Hall-effect sensors which measure the strength of a magnetic field. The magnet is implanted in the bone on one side of a joint, and the sensors are implanted in the bone on the other side of the joint. The sensors are used to detect movement of the magnet which is related to the angle of the joint. Work has been directed in five main areas: 1) theoretical calculation of magnetic fields to predict sensor output; 2) empirical testing of sensor and magnet configurations; 3) development of automatic testing and calibration procedures; 4) refinement of an external transducer based on the configuration results; and, 5) tentative design for the implantable package.

Results—Initial design of the sensor has been completed and it has been fabricated for bench testing. For implantation, we plan to package the magnet and sensors in titanium to provide a lifetime that will exceed the lifetime of the user.

Future Plans—Fabrication of the implanted sensor will continue to be followed by bench and *in vivo* testing.

B. Upper Limb Applications

Functional Neuromuscular Systems (FNS) for Upper Extremity Control

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Purpose—The purpose of this research is to develop and implement systems to restore functional control of the upper extremity in C5 and C6-level quadriplegic individuals through electrical activation of the paralyzed muscles.

Progress—Clinical evaluation of the functional electrical stimulation (FES) system for restoration of grasp and release in the high-level quadriplegic individual has demonstrated enhancement in performing activities of daily living. In this study, 25 subjects, who had been provided with the Case Western Reserve University/VA FES Hand System, were asked to perform certain activities of daily living both without and with their system, and their performance was compared. Subjects who used the FES system were able to successfully complete more tasks with the orthosis than without.

The system that was evaluated was one which provided palmar and lateral prehension and release by electrical stimulation of the appropriate forearm and hand muscles. It consisted of the input command control device, the microprocessor-based control and stimulation unit, and the electrode system. For most of the subjects, the input control device was a shoulder position sensor, which measured protraction, retraction, and elevation depression of the shoulder opposite to the stimulated hand. Alternatively, some subjects used switch control to grade the strength of stimulation. The control device was attached to the stimulation unit by wiring beneath the clothing. The electronics module was attached to the wheelchair. The electrode system generally was chronically-indwelling percutaneous wire electrodes. However, in one subject, a multichannel implantable stimulator was surgically placed in the axillary area, with lead wires tunneled subcutaneously to the muscles of the forearm and hand.

We compared the performance of subjects with and without the system in different tasks of eating, hygiene, and office tasks. In each case, the subject was asked to perform a task in entirety, in order to be called a success. The tasks examined were: moving a book, answering a telephone, manipulating a computer disk, writing, brushing teeth, drinking from a glass and a mug, eating finger foods and eating with a utensil.

Results—In comparing the subject's performance without the FNS system, the subjects were instructed to wear their best orthosis for performing the task. The results show that in no case did a subject lose function. That is, if they could perform the task without the FNS system, it could always be performed with the FNS system. In general, subjects could perform many more of the activities completely with the FNS system than without. In comparing the performance of subjects with an injury at C5 versus those with injury of C6, we found that those with C5 function had a greater increase than the number of tasks that they could successfully complete. The results of the tests, which have been subjected to statistical analysis, demonstrate that the FNS system is successful in enhancing the ability of users to independently perform certain activities of daily living.

The implantable stimulator system had been placed in one subject in August 1986. In July, 1988, the device was replaced, due to a higher-than-anticipated power transmitted to the device. The device was operational at removal, and all electrodes were intact. Thresholds had remained essentially constant over the nearly 2-year period. Replacement of the device enabled us to utilize an implant which required a considerably lower level of transmitted power. The results of the implantable system have been highly satisfactory. The patient reports a high degree of preference for its use as compared to the percutaneous wire electrodes, because it has removed the percutaneous skin interface and associated maintenance issues, and is simpler to don. No problems with leads or electrodes have been experienced with this system.

Future Plans/Implications—Our future research goals are to extend the evaluation of the implantable stimulator systems to additional subjects and to refine the evaluation procedures. The implantable system to be utilized will be the one that was used in the first subject. Evaluation of the systems will continue. The tests to be performed include the common object test previously described, with an expanded scope. The test that was performed has deficiencies in the number of tasks that were performed and its analysis, which has not enabled us to measure the quality of performance or patient preference. We are also performing a standard object test in which we will be able to quantitatively assess performance in more detail. Internal monitoring systems which have been incorporated into the stimulation hardware will enable us to determine user/usage patterns both for muscle conditioning and for function.

Publications Resulting from This Research

Functional Electrical Stimulation: Current Status and Future Prospects of Applications to the Neuromuscular System in Spinal Cord Injury. Peckham PH. *Paraplegia* 25(3):274-288, 1987.

Restoration of Functional Control by Electrical Stimulation in the Upper Extremity of the Quadriplegic Patient. Peckham PH, Keith MW, Freehafer AA. *J Bone Joint Surg* 70A(1):144-148, 1988.

Functional Neuromuscular Stimulation Neuroprostheses for the Tetraplegic Hand. Keith MW, Peckham PH, Thrope GB, Buckett JR, Stroh KC, Menger V. *Clin Orthop Rel Res* 233:25-33, 1988.

Restoration of Upper Extremity Control with Functional Electrical Stimulation

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Sponsor: *National Institutes of Health, Neural Prosthesis Program*

Purpose—The purpose of this project is to develop enhanced systems for control of the upper extremity using functional electrical stimulation. The research consists of three projects: I. Control and Coordination of Hand Movement; II. Control of Elbow Extension; and, III. Command Control Signal Enhancement.

I. Control and Coordination of Hand Movement

Progress—The force vectors of various electrically-stimulated muscles controlling the fingers and hand have been studied in human spinal injury subjects to determine optimum ways of coordinating movement of the digits in restoration of hand function. In these studies, the isometric force developed by the electrically-stimulated muscles is measured isometrically with the forearm stabilized in a cast structure and the digits are placed against an apparatus to measure force. We measured the input/output properties of the muscles with stimulation delivered either via percutaneous electrodes or an implanted stimulator. Muscles were characterized for their recruitment gain, linearity, threshold, isolation of the stimulation to the target muscle, and joint position dependent input/output characteristics. Selection from among several electrodes serving similar functions is assisted through a process which assigns to each electrode a rating and a scale of the relative importance of the factor to each muscle group.

We have developed methods to coordinate the action of muscles together in order to provide coordinated movement of the hand. The procedures used in developing the coordinated movement are partially automated. The electrode parameters are then installed in the hand coordination control programming system. This programming system consists of desired grasp templates for both lateral and palmar prehension. The resulting movement and grasp are then visually observed and/or measured, and further refinement is introduced, if necessary, to provide finer movement. This procedure has been introduced into the setup of clinical systems in outpatient subjects.

Future Plans—We plan to continue the development of the coordination procedure to incorporate more extensively the use of muscle force vectors in the automated grasp procedure. Furthermore, we plan to more fully automate the hand-grasp setup in order to expedite its use with collaborating researchers.

II. Control of Elbow Extension

Progress—A technique has been developed to control elbow position in the C5 quadriplegic by electrical stimulation of the triceps muscle. The elbow position control system is activated by the position of the humerus in abduction and external rotation. That is, the position of the humerus is the command which is used to regulate the stimulus to the triceps muscle; the greater the shoulder abduction and external rotation, the greater the magnitude of the stimulus applied to the triceps muscle. A biomechanical model of the forearm and hand is used to determine the magnitude of the stimulus applied to the triceps, which will counteract the forearm mass and the mass of a nominally-weighted object held in the hand. The stimulus applied is always sufficient to provide full extension of the elbow. In the event that the user wants to obtain a partially flexed elbow, he voluntarily activates the elbow flexors to overcome the triceps stimulation.

The elbow extension system has been implemented into the arms of three C5 quadriplegic subjects. Tests were performed in which the subject was asked to reach positions in space with his hand above the horizontal level with various weights attached in the hand. In over 95 percent of the cases, the subject was able to perform the movement with the stimulation, which could not otherwise be performed without, thus demonstrating the feasibility of this concept.

Future Plans—The system for elbow position control will be implemented into a patient-portable system for evaluation with the hand grasp system.

III. Command Control Signal Enhancement

Progress—Shoulder position control has been evaluated as a means of providing command control signals for control of hand grasp. The general principle is to utilize protraction and retraction of the shoulder as the proportional command source, and elevation or depression as a logic command by which the proportional command source is overridden.

The command movements of normal and quadriplegic subjects with various levels of injuries were studied to determine optimal ways of processing the shoulder signals, in order to provide the highest resolution command and the fewest inadvertencies in generating lock command. We found that there was generally a contamination in the vertical movement with the horizontal component and similarly in the horizontal movement. This contamination affected the ability of the subject to perform the hold at the desired proportional command. A signal-processing technique was developed to enable the user to perform both the proportional and logic command signal generation reliably. The system software in the user-portable system has been rewritten to incorporate the signal processing techniques developed in this study.

Future Plans—We presently are evaluating the revised command signal processing techniques in the portable outpatient systems to identify remaining deficiencies in the command control procedure.

Functional Electrical Stimulation (FES) for Upper Limb Strengthening in Traumatic Quadriplegia

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Sponsor: *Adelaide Bone and Joint Foundation*

Purpose—The hypothesis of this study was that FES-assisted exercising of partially paralyzed upper-extremity muscles would result in significantly greater muscle strength in the arms of spinal cord injured quadriplegics than equal periods of conventional isotonic exercise.

Progress—Our approach was to study single muscles in seven subjects in a cross-over design consisting of equal periods of FES-assisted exercise and conventional exercise. This project is now complete.

Results—The conclusions of the study were that for our client group and exercise regime, neither FES-assisted exercise nor conventional exercise produced improvements in maximum voluntary force which were significant either statistically or functionally.

Future Plans/Implications—The results, although disappointing, have helped our clients to be more realistic about the potential therapeutic benefits of FES.

Publications Resulting from This Research

Functional Electrical Stimulation for Upper Limb Strengthening in Traumatic Quadriplegia. Seeger BR, Law D, Creswell JE, Stern LM, Potter G. *Arch Phys Med Rehabil* (in press).

C. Lower Limb Applications

Effectiveness of Transcutaneous Stimulation in Activating Skeletal Muscle

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B342-RA)*

Purpose—At the beginning of this year, we extended our previous studies on the tibialis anterior (TA) to the medial gastrocnemius (MG) muscle as our model for a "fast" muscle. We hypothesized that the MG would atrophy significantly upon immobilization. We completed the MG immobilization study, and demonstrated a significant decrease in maximum tetanic tension. However, as we began the stimulation studies, we felt it necessary to repeat the "calibration" experiments which were previously performed on the TA. To our surprise, we demonstrated that: 1) it is difficult, if not impossible, to activate all of the MG muscle fibers using transcutaneous stimulation; and, 2) the amount of tension generated by the MG by 50 Hz functional electrical stimulation (FES) was less than 3 percent of P_0. At this point, we believe that this is due to the fact that the tibial nerve is deeper than the peroneal nerve, making it difficult to activate the nerve, and thus, the entire muscle cross-section.

Progress—In order to determine whether this finding applied to the clinical situation, we applied FES to the quadriceps and anterior compartment muscles of 20 men and 10 women, and found that FES activated the muscles to only about 30-50 percent of the individual's maximum voluntary contraction (MVC). It was possible to stimulate men to a significantly greater proportion of their MVC ($p<0.01$) than women.

Results—We demonstrated that, while 10 Hz and 50 Hz FES did not strengthen the TA, it did have a differential effect on the ipsilateral, unstimulated soleus muscle. This result implies that the passive stretch is an important factor in maintaining muscle strength, and is "good news" for therapists.

Publications Resulting from This Research

Differential Response of the Dog Quadriceps Muscle to External Skeletal Fixation of the Knee. Lieber RL, Friden JO, Hargens AR, Danzig LA, Gershuni DH, *Muscle and Nerve* 11:193-201, 1988.

Differential Effects of 10 Hz and 50 Hz Stimulation of the Tibialis Anterior on the Ipsilateral, Unstimulated Soleus Muscle. Lieber RL, Ferro TD, Hargens AR, *Exp Neurol* 100:426-435, 1988.

Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics

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Purpose—The long-term objective of this program is to design and implement a functional neuromuscular stimulation (FNS) system which will restore to paralyzed individuals the ability to accomplish functional tasks using crutches, including walking on levels and ramps, and climbing and descending stairs. The studies performed during the past year have centered on development of hardware, software and muscle implantation methods for practical FNS systems.

Progress—*Muscles and electrodes.* Percutaneous intramuscular electrodes were modified to include a prolene core and a stronger anchoring tip; the implantation method was modified to assure greater accuracy in placement of the electrode following successful probing of the muscle. Twelve months' experience with the prolene core electrode showed a greater resistance to breakage following the same period of early movement experienced without the core. Forty-seven percent of prolene core electrodes survived, while only 25 percent of non-core electrodes survived after one year.

Muscle strength studies were done of knee and hip extensors and hip flexors activated by electrical stimulation. Further response and relaxation times were determined at different frequencies.

Control of stimulation. Open-loop stimulation patterns for walking were triggered by detection of threshold pressure on force-sensing resistors placed under the heel. The main emphasis in open-loop pattern modifications have been in control of plantar flexors for push-off and control of the knee during the stance phase. These have produced smoother, more natural gait, but were difficult to control in open-loop.

Feedback control of hip and trunk motions has been shown to provide improved stance stability during performance of various tasks, with reduced sensitivity to perturbations in both the coronal and saggital planes. Reduced arm support and reduced levels of stimulation have been observed. A discrete-event model of paraplegic gait has been developed, based on analysis of open-loop electrical stimulation patterns for walking. This model has been confirmed by observation of user motion and will provide a framework for future development of closed-loop FNS walking, with and without braces.

External hardware and orthoses. A new laboratory stimulation system was designed and built. It permits walking trials over a 50-foot walkway while the subject's stimulation is controlled from the laboratory computer. This arrangement allows adjustment of stimulation patterns for refining gait in less than one minute.

The muscle stimulator was redesigned to control 48 channels and to be usable either as a portable, or as part of the laboratory system. An instrumented insole for detecting foot floor contact and triggering the next step was developed and tested. A thumb-manipulated joystick control was developed to give a more intimate command input.

A hybrid knee-ankle-foot brace (originally developed at the University of Strathyclyde) which works together with FNS has been built and tested. A closed-loop bang-bang controller used a measurement of knee extension moment to switch on and off activity of the quadriceps muscles. Potential benefits of using hybrid orthoses include: delaying the onset of muscle fatigue, preventing hyperextension of the knees, and extending the standing duration of paraplegics using FNS.

FNS-Effects Upon Venous Pooling in Mobility-Impaired and Geriatric Patients (Project Extension)

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Purpose—The overall goal is to evaluate the acute effects of functional neuromuscular stimulation (FNS)-induced contractions of leg muscles upon central and peripheral hemodynamic responses to determine if venous pooling/stasis can be minimized and/or reversed in mobility-impaired and geriatric patients. Specific objectives are: 1) to evaluate the effectiveness of this FNS application for facilitating circulation during acute bouts of head-up tilt, sitting, and standing; and during prolonged bouts (<30 min) of upright posture (sitting and standing); 2) to determine if FNS-induced contractions and facilitated circulation can improve arm-crank ergometer exercise and actual wheelchair locomotive performance (in the upright sitting posture); and, 3) to compare the effectiveness of lower-extremity FNS-induced static contractions with commonly-used methods of alleviating venous pooling and stasis (i.e., pressure boots and support hose).

Progress—At least 60 individuals will serve as subjects during this 3-year study. Experimental groups will consist of younger and older spinal cord injured, geriatric, other mobility-impaired subjects, and able-bodied control subjects. Eight-channel neuromuscular stimulators have been specially designed and constructed to alternately contract thigh (quadriceps and hamstring) and calf (tibialis anterior and gastroc-soleus) muscle groups bilaterally. This FNS is used to activate the skeletal muscle pump and enhance return of venous blood to the heart during various postural maneuvers and exercise tests. Typically, 1.5-second contraction/relaxation intervals are used.

Preliminary Results—As reported in our 1987 Rehabilitation Research & Development Progress Report and recent publications, FNS-induced static contractions of leg musculature apparently activate the skeletal muscle pump and significantly increase ventricular stroke volume and cardiac output in SCI and able-bodied subjects during passive head-up tilt and during arm-crank exercise (when tilted to 30 degrees).

Future Plans/Implications—If this FNS application can minimize venous pooling in the legs and improve circulation to exercising arm muscles, it may be able to improve arm exercise capacity, reduce the stressfulness of manual wheelchair locomotion, and improve the tolerance of prolonged upright postures. Future medical and rehabilitative applications may also include prevention of deep venous thrombosis/pulmonary embolism in immobilized or post-surgical patients and treatment of orthostatic hypotension, excessive pedal edema, and decubitus ulcers in susceptible individuals.

Publications Resulting from This Research

Hemodynamic Responses During Electrically Induced Leg Exercise and Arm Crank Ergometry in Lower-Limb Disabled Males. Davis GM, Servedio FJ, Glaser RM, Collins SR, Gupta SC, Suryaprasad AG, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:591-593, 1987.

Central Hemodynamic Responses to Lower-Limb FNS. Glaser RM, Rattan SN, Davis GM, Servedio FJ, Figoni SF, Gupta SC, Suryaprasad AG, *Proceedings of the 10th Annual Conference of IEEE/EMBS* 615-617, 1988.

A Multichannel Stimulator for FNS Applications. Glaser RM, Collins SR, *Proceedings of the ICAART Conference*, Montreal, 344-345, 1988.

FNS-Assisted Venous Return in Exercising SCI Men. Figoni SF, Davis GM, Servedio FJ, Gupta SC, Suryaprasad AG, Rodgers MM, Ezenwa BN, *Proceedings of the ICAART Conference*, Montreal, 328-329, 1988.

Cardiovascular Responses to FNS-Induced Isometric Leg Exercise During Orthostatic Stress in Paraplegics. Davis GM, Figoni SF, Glaser RM, Servedio FJ, Gupta SC, Suryaprasad AG, *Proceedings of the ICAART Conference*, Montreal, 326-328, 1988.

Cardiovascular Responses to Exercise in Young and Middle-Aged SCI Subjects. Rodgers MM, Figoni SF, Glaser RM, Davis GM, Servedio FJ, Suryaprasad AG, Gupta SC, Ezenwa BN, *Proceedings of the ICAART Conference*, Montreal, 160-161, 1988.

FNS-Enhancement of Central Hemodynamic Performance in Paraplegics During Tilting. Figoni SF, Davis GM, Glaser RM, Servedio FJ, Suryaprasad AG, Gupta SC, *Am Spinal Injury Abs Dig* 153, 1988.

Functional Electrostimulation

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Sponsors: *Innovative Research Programme/Aids for the Handicapped; Association for Technical Sciences, Utrecht*

Purpose—This project is concerned with functional electrostimulation of the lower extremities with automatic adaptation to inter- and intra-patient variability.

Patients with leg paralyses as a consequence of defects of the central nervous system can sometimes be given the (partial) functional use of the legs by means of artificial stimulation of the peripheral nerves.

This research is concerned with the development and evaluation of equipment and practice procedures for transcutaneous stimulation for movement from sitting to standing up, and limited forward movement for, among others, paraplegia patients. This implies: 1) development of stimulation patterns; 2) development and evaluation of test and practice protocols; 3) construction of a comfortable leg corset with stimulation electrodes; and, 4) development of mechanical aids.

Progress—Clinically usable closed-loop controls for standing up and standing are being developed. The first experiments are promising.

Results—A first version of the treatment protocol has been finished and an experimental cycling-ergometer proved to be satisfactory and will be developed further.

Publications Resulting from This Research

Stand Up with Functional Electrostimulation. Van Alste JA, Ten Brug H, Mulder AJ, *Proceedings of the XI International Congress of Biomechanics*, Amsterdam, 1987.

Closed Loop Control of Standing and Standing-Up. Mulder AJ, Van Alste JA, Hermens HJ, Zilvold G, *Proceedings of the EEC Workshop on Restoration of Walking Aided by Functional Electrical Stimulation, COMAC BME*, Enschede, 37-46, 1987.

Control of Standing Using Functional Electrical Stimulation. Mulder AJ, Verheijen JME, Hermens HJ, Van Alste JA, *Proceedings of the XI International Congress of Biomechanics*, Amsterdam, 217, 1987.

An Improved Strategy to Minimize Muscle Fatigue During FES Induced Standing. Mulder AJ, Hermens HJ, Van Alste JA, Zilvold G, *Proceedings of the 7th International Congress of the ISEK*, Enschede, 1988.

FES-Powered LSU Reciprocal Gait Orthoses: A Practical Walking System for Paraplegics

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Sponsor: *Louisiana State University Medical Center; National Science Foundation*

Purpose—The LSU-RGO (reciprocal gait orthoses) was developed into a practical and useful device that allows paraplegics (among other disability categories) to maintain upright posture effortlessly, keep balanced and stable, initiate the swing phase with one leg simultaneously with push-off with the contralateral leg.

Progress—After 12 years of experience with the brace, more than 2,000 patients have been fitted in the U.S., England, Canada, and the Netherlands.

To reduce the energy consumption required by the patient, a 4-channel FES system was developed to initiate hip flexion and simultaneous contralateral hip extension. One-year evaluation of ten paraplegics ranging in level of injury from C-4 to T-1!, revealed that a practical solution to the simple locomotion needs of such patient category is at hand.

Efforts are being made to have the stimulators commercially available. The LSU-RGO is already available to order from Durr-Filhauer, Inc., of Chattanooga, TN.

Implantable Gait Stimulation System

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—An implantable 8-channel stimulator is being developed to supplement intact neural control of gait in stroke and spinal cord trauma patients. The implantable stimulation system can generate charge-balanced biphasic pulses from 0-2.25 mA in 16 steps. Pulse width is controllable from 30-300 μsec in 0.17 μsec steps.

Progress—The stimulator utilizes a 3-chip set of integrated circuits developed at Stanford University Integrated Circuits Laboratory. These chips are enclosed inside a titanium, hermetically-sealed enclosure, with 8 tantalum feedthroughs for electrodes, and 3 feedthroughs for antenna connections.

The device receives its information and power from a 20 MHz transmitter modulated with an External Timing Control Code, composed of two words, a Transition Word and an Amplitude Word. The Transition Word is used to change the state of any of the 8 channels. If a One occurs in channel bit positions, then that channel output cycles to its next state of 3 states, sinking current, sourcing current, and charge balancing. The Amplitude Word selects the current amplitude of the state sequency of a given channel. It has 3 bits to individually address the 8 channels, 4 bits to adjust the current magnitude, plus one more bit to set the current polarity.

Pulse width is controlled by the external controller's timed delivery of commands to change the state of a particular channel. The external controller uses a formatter circuit running with a clock rate of 6 MHz, and can thus time the delivery of commands to the implant with a resolution of 1/6 μsec for very fine resolution.

Publications Resulting from This Research

Development of an Implantable and Percutaneous Electrical Stimulation System for Gait Applications in Stroke and Spinal Cord Patients. Meadows PM, McNeal DR, Su NY, Tu WW, *Proceedings of the 9th International Symposium on External Control of Human Extremities*, Dubrovnik, Yugoslavia, 51-64, 1987.

Development of an Implantable and Percutaneous Electrical Stimulation System for Gait Applications in Stroke and Spinal Cord Patients. Meadows PM, McNeal DR, Su NY, Tu WW, *Proceedings of the 9th Annual IEEE-EMBS Conference*, Boston, MA, 618-619, 1987.

Programming System for Functional Movements

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Purpose—A computer-based programming system is being developed to support research with a newly-developed 8-channel implantable stimulation system and an 8-channel percutaneous external stimulator for gait assist in hemiplegic patients.

Progress—During gait training with this multichannel system, the physiological state of the patient (while parameters of stimulation are being determined) is not stable; therefore, these parameters must be quickly viewed and modified while they are still appropriate for the measured state of gait performance. To achieve this, the programming system utilizes a very high speed color video graphics subsystem allowing the clinician to quickly determine new gait stimulation parameters.

Extensive use of nested menus facilitates the user interface and a novel database architecture is employed to allow large amounts of stimulation data to be stored and retrieved readily. The system is implemented on a Digital Equipment Corporation PDP 11/23+ computer, written in the C language for the RT11 operating system. The graphics subsystem is manufactured by Parallax, has a resolution of 1280 by 1024 by 8, and has a drawing speed of 50,000 vectors/second.

Publications Resulting from This Research

Development of an Implantable and Percutaneous Electrical Stimulation System for Gait Applications in Stroke and Spinal Cord Patients. Meadows PM, McNeal DR, Su NY, Tu WW, *Proceedings of the 9th International Symposium on External Control of Human Extremities*, Dubrovnik, Yugoslavia, 51-64, 1987.

Development of an Implantable and Percutaneous Electrical Stimulation System for Gait Applications in Stroke and Spinal Cord Patients. Meadows PM, McNeal DR, Su NY, Tu WW, *Proceedings of the 9th Annual IEEE-EMBS Conference*, Boston, MA, 618-619, 1987.

Sensors for Control of Gait Stimulation Systems

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Purpose—Sensors are needed to trigger, initiate, and terminate electrical stimulation to paralyzed muscles in gait stimulation systems. Signals from these sensors must occur consistently in each gait cycle. Minimally, at least one trigger should occur every 25 percent of the gait cycle in order to provide adequate control. The sensors must also be cosmetically acceptable for use outside of the laboratory.

Progress—Initial systems will be radio-frequency coupled, which will enable external sensors to be used to trigger stimulation, but sensors that could be implanted inside the body were also investigated in this study. From results of previous studies, and our own analysis of spinal cord injured (SCI) gait, the external sensors selected were: footswitches under the heel, first and fifth metatarsal, and the great toe; and, the load cells mounted on the crutches. Potentially implantable sensors selected were: bilateral electromyographs of the latissimus dorsi, erector spinae, posterior deltoid, lateral head of the triceps, and vertical accelerometers.

In this study, 8 incomplete SCI persons were instrumented with the above-mentioned sensors and tested during level and ramp walking. The sensor's onset and offset signals varied between subjects, but was consistent within each subject. Consistency of the sensors was measured by the standard deviation of the onset and offset signals. The most consistent sensors were the heel switch (8/8), fifth metatarsal switch (7/8), first metatarsal switch (7/8), load cells in the crutches (7/8), vertical accelerometers (5/8), latissimus dorsi (4/8) and the erector spinae (4/8). The external sensors occurred at least every 25 percent of the gait cycle; however, the potentially implantable sensors occurred only every 50 percent of the gait cycle.

Control of the Paralyzed Human Leg

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Purpose—By providing active control of paralyzed muscles, electrical stimulation can help persons with neurological impairments walk more easily with less bracing. The success of this application depends upon our ability to select control signals for each individual to produce and sustain coordinated movement patterns to achieve the desired functional result.

Progress—Techniques for producing repetitive movements of the leg have been studied in an agonist-antagonist model in which subjects were seated and movements were restricted to free-swinging movements at the knee.

In preliminary experiments using normal subjects, electromyographic recordings were used to document the activity of the quadriceps and hamstring muscles during various repetitive movement patterns. Co-contraction of the quadriceps and hamstring muscles were never observed in any of the subjects.

Results—Four paraplegic subjects were tested before and after an 8-week exercise program in which muscles were cyclically stimulated for up to 2 hours per day. Muscle endurance to electrical stimulation increased significantly in 3 of the 4 subjects. Muscle strength decreased following 1 week of exercise, then slowly increased during the next 7 weeks to levels close to the pre-exercise values.

A programming system, consisting of a computer-controlled interactive graphics system and a laboratory stimulator, was used to select control sequences for the quadriceps and hamstring muscles to match selected movement patterns. Accurate matches were achieved using an interactive procedure in which estimates of the control were tried, and then modified until the movement matched the desired pattern. Control sequences could be used on subsequent days when adjusted by an appropriate gain. Repeated responses were extremely consistent, but there was a progressive degradation during extended trials which demonstrated the limitations of open-loop control, even in exercised legs.

Several adaptive controllers were evaluated using an analytical model of the freely-swinging leg acted upon by an agonist-antagonist muscle pair. An adaptive control scheme which does not require knowledge about the plant parameters produced a control sequency which matched and sustained various desired movements. This scheme has not yet been tried on human subjects.

Publications Resulting from This Research

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Isolation of EMG from FES Stimulation Artifact

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Electromyograms (EMG) and stimulus artifact generated during electrical stimulation with various combinations of stimulation electrodes were recorded from a subject with previously-implanted epimysial electrodes on the surface of the gluteus maximus (G MAX) and gluteus medius (G MED) muscles.

Methodology—A quiet resting run was performed to obtain baseline levels on all channels. Two series of tests were conducted with the patient lying supine on a test table. In the first, EMG signals were recorded from the TFL, SART, IL, RF, G MED and G MED SUB Q electrodes. The second series, BFLH and G MAX electrodes, were substituted for TFL and G MED. Four stimulation tests were conducted, each with one of the following electrode combinations: monopolar G MED epimysial 1 and surface reference; monopolar G MED epimysial 2 and surface reference; bipolar G MED epimysial 1 and 2; bipolar G MED epimysial 1 and G MAX epimysial 1. A similar set of tests was conducted for the hip extension series, with stimulation of the G MAX in place of the G MED.

Results—All data were plotted for visual observation and analysis. Regardless of the configuration of the stimulating electrodes, a typical data set included high or moderate levels of EMG superimposed on stimulus artifact from some electrodes and others with either EMG and no stimulus artifact or stimulus artifact without EMG.

Computer processing of the data involved rectifying and integrating over a 0.01 sec interval. In all cases, signal that dropped below a baseline level established from the resting run was eliminated. From a data channel that visually showed mostly stimulus artifact (stim detection channel, or SDC), a threshold was passed above all low level signal. For all channels, the data were removed for intervals where the signal on the SDC was below the threshold. This left only signal occurring at the time of a stimulus pulse. Mean values were obtained for each channel. A ratio of the amplitudes (amplitude ratio) from the SDC to each respective channel was determined. The amplitude of the original integrated data was scaled to the amplitude of the SDC by multiplying each interval value by the respective amplitude ratio. The intervals where the SDC signal exceeded the threshold were subtracted from the values for the same intervals on all other channels of data.

A visual examination of graphs of the processed data showed most of the artifact removed. This technique, however, suffers from two problems: the stimulus artifact pulses do not line up consistently with the integration intervals resulting in spillover to adjoining intervals and fluctuations in the stimulus amplitude from pulse to pulse create error based on the amount of this deviation from the mean values subtracted.

Future Plans—These problems will be corrected in future work by employing a technique reported by R. Bloch to subtract the EKG signal from respiratory muscle EMG. This technique utilizes recursive digital filters to locate the center of each artifact pulse and performs a least-squares subtraction of averaged (corrected for amplitude fluctuations) artifact pulses from the desired EMG. Computer programs to implement this very promising technique are being written for our VAX 11/750 computer.

VIII. Functional Assessment

Dataglove Semi-Automated Hand Function Evaluation System: A Pilot Study

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Purpose—This study will address three major problems in treating hand impairment: 1) assessing the exact extent of the impairment; 2) deciding the best therapy for the impairment; and, 3) evaluating the results of therapy, whether by surgery or rehabilitation. Present methods of hand evaluation are time-consuming, nonquantitative and static, lacking means for measuring position and force while the hand is in motion. New dynamic measurement and information processing modalities will improve the collection of data from patients before and after treatment, and permit the comparison of current performance with prior and projected capacity. The effects of tendon transfer surgery, hand therapy to improve range of motion, and external splinting can be evaluated using a library of normal and impaired hand motions.

One component of a system to better assess hand function is the DataGlove (VPL Research, Redwood City, CA) which looks and feels like an ordinary light fabric glove, but includes bending sensors connected to a computer. The computer uses the outputs of these and a separate spatial position sensor to calculate the angles of each finger joint and the overall position of the hand. It can display a picture of the hand with fingers bending to grasp and manipulate a real or simulated object, and additionally, can tabulate position in near real-time.

The DataGlove will be used as part of a three-phase program to: 1) modify present software to better acquire data from abnormal hands; 2) record data from normal hands while performing tasks derived from the Jebsen test; and, 3) evaluate patients suffering from several types of impairment due to high spinal cord injury, peripheral nerve injury, tendon injury or arthritis. Research is being undertaken to: 1) improve upon the DataGlove's ability to detect finger and thumb abduction and adduction; 2) calibrate the DataGlove's calculated finger angles against an absolute standard; and, 3) add force measurement capability to the system.

The DataGlove has thus far been used to gather single-finger bending angle data on normal subjects. This portion of the study is being repeated for all 5 fingers, and compared to standard goniometric measurements for the resting position of each joint, the maximum active extension and flexion (opening and closing the hand), and maximum passive extension and flexion. A data sheet printed by the MacIntosh computer connected to the DataGlove is then compared to the manually-transcribed goniometric data sheet prepared by the therapist.

Assessment of the Swallow Reflex in Patients with Dysphagia

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Purpose—Although dynamic radiographic methods are the best means of assessing the competency of a swallow, repeated X-ray for assessment of improvement in swallowing may not be ethically justifiable nor conveniently arranged. The purpose of this project is to develop a non-radiographic method by which investigators can study certain aspects of swallowing with a variety of repeated measures designs. Ultimately, the results of this investigation will provide information for determining appropriate rehabilitation techniques for patients with dysphagia.

This study has three objectives. Objective I will confirm the use of the electroglottograph (EGG) and an electronic pressure transducer as a valid and reliable method of measuring the time (T_{sw}) between completion of the oral phase of the swallow (T_1) and elevation of the larynx (T_2).

Objective II will study healthy young adults and healthy elderly adults in order to identify possible age-dependent differences in T_1-T_2. Analysis of the effect of age on swallow (T_{sw}) will be conducted by a 4-way ANOVA using multiple observations per subject with three temperatures and two viscosities of material. Tests for interaction and main effects will be performed.

Objective III will test the effectiveness of current treatments in three subpopulations of patients. These patients will be taken from three general diagnostic groups; those with a swallowing disorder subsequent to: 1) surgery for oral/pharyngeal cancer; 2) CVA; and, 3) degenerative neuromuscular disease. A $2 \times 2 \times 3$ contingency table will be prepared to evaluate the rate of improvement for T_1-T_2 across treatment groups and diagnoses. A log linear model will evaluate whether there is a significant association between improved status and treatment that is independent of diagnosis.

Progress—The primary requirement for this investigation was increasing the sensitivity of the EGG, thus making it capable of detecting the low frequency displacement changes characteristic of the larynx during a swallow. We have almost achieved this level of sensitivity. Once achieved, we will begin using the EGG for data acquisition.

An electromyographic (EMG) study was performed to determine which non-swallowing tasks produce significant levels of activation in the superior pharyngeal constrictor muscle of normal subjects. The study of normal subjects was important because, without the normative data, one would not know whether the absence of a muscle response in a patient was expected for a particular task or if it was a manifestation of pathology. Bipolar hookwire electrodes were inserted in the superior pharyngeal constrictor muscle. Electrode placement was controlled. Each subject performed 2 reflexive tasks, 6 voluntary tasks requiring phonation, and 4 nonspeech voluntary tasks. The EMG signal was rectified, integrated, and the resulting value was then transformed by taking its natural logarithm. An ANOVA was performed and a linear model was estimated.

Results—The magnitude of the EMG activity was related to the location of the electrodes. There was a strong trend in the amplitude of EMG activity in relationship to task. The reflexive tasks of swallowing and gagging resulted in the most EMG activity. The gag produced about 60 percent of the activity produced by a swallow. A "modified valsalva" and the hard /k/ as in the final position of "hawk" produced about 20 percent of the activity produced in the swallow. These findings suggest that there may be a hierarchy of exercises that can be used for treating pharyngeal constrictor paresis in dysphagic patients.

Future Plans—It will be necessary to verify to what extent the neural systems involved in non-reflexive activation of the pharyngeal constrictor muscles are intact in various subpopulations of dysphagic patients. This could be tested using this quantitative measurement of pharyngeal EMG with a repeated measures design.

Development of an Interactive Arm Ergometer and Computer Graphics System

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Purpose—The purpose of this project is to develop an arm ergometry system that provides a more intrinsically motivating exercise experience than existing ergometers. It is hypothesized that such an enhancement would improve the frequency with which aerobically beneficial exercise intensity and duration is pursued by hospitalized veterans. Regular aerobic exercise has been established to induce many positive physiological and psychological changes. However, aerobic exercise modalities for the lower-extremity impaired are limited. Arm ergometers are widely available and potentially effective, but they involve rather boring, repetitive activity. Thus, they require a strong system of extrinsic reinforcements for adequate exercise intensity and duration to be maintained. Since many VA hospital patients are not strongly motivated by such extrinsic goals as maintaining optimal fitness or athletic performance, etc., the task of upper body ergometry must be made more interesting so as to inherently elicit appropriate exercise responses.

The project involves the development and testing of a computer game which will be displayed on a high resolution color monitor positioned in front of the ergometer during exercise. The graphic scenarios generated will be comparable to those that presently exist for home computers. Data regarding their user's prescribed heart rate will be fed into the computer. The scenario will then act to maintain a level of challenging engagement which will facilitate the prescribed exercise response. The game will have the following attributes: 1) the display will always reflect a level of task difficulty that can be successfully performed by the user, since the work output necessary to be successful is not predetermined externally, but rather is internally based; and, 2) unfavorable scenario outcomes will occur when the user's heart rate drops below or exceeds the prescribed heart rate range. Thus, fatigue alone will not bring about failure and potentially dangerous, high heart rates will not be positively reinforced. The user's heart rate, blood pressure, and rate pressure product will be monitored to prevent excessive cardiovascular stress.

The project is specifically concerned with the following questions: 1) To what extent will use of the exercise modality increase the user's arm ergometry exercise intensity and duration? 2) To what extent will use of the exercise modality increase the user's functional capacity for independent wheelchair mobility? and, 3) To what extent will use of the exercise modality improve user fitness with regard to resting heart rate and blood pressure and steady state heart rate, blood pressure response and lactate clearance during submaximal arm-cranking exercise?

Progress--To date, most essential equipment has been procured, the actual game scenario has been determined, and software development has been initiated. Pilot testing of the game began in December, 1988. The experimental testing of the exercise modality using Danville VA Medical Center patients began in the first quarter of 1989.

Development of the Occupational Therapy Comprehensive Functional Assessment (OTCFA)

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Sponsor: *American Occupational Therapy Foundation*

Purpose—Over the past decade, the American Occupational Therapy Association has acknowledged the significant inconsistency and splintered approach of assessment in occupational therapy. To remedy the problem, it has promoted research to evaluate the significance of the problem, and begun to implement strategies for assuring a better continuity of evaluation between service delivery settings and instituting a more comprehensive approach for evaluating the efficacy of therapeutic intervention. A recent step in the development of a better comprehensive performance evaluation has been the formulation and field-testing of the Occupational Therapy Comprehensive Functional Assessment (OTCFA).

Progress—Over the past year, a complete version of the OTCFA has been nationally field-tested with a cross section of diagnostic populations whom occupational therapists treat, and service delivery settings where occupational therapists work. Several data sets have been collected. One was obtained to examine the administrative validity of the assessment (including the face validity, time required to learn and common use of the assessment, and perceived value of the assessment by clinicians after using it). A second data set was collected in order to statistically scrutinize items within the assessment, and a third to assess alternate form reliability. Additionally, pilot test-retest and inter-rater reliability data have been collected.

Results—Field-test data have verified the need and utility of the assessment, supported its conceptual hierarchical organization and content of the OTCFA. Analysis of data from pilot reliability studies revealed significant volatility of the scores when therapists documented function without evaluations containing direct observation protocols. This has provided a basis for the assessment's current revision and for designing ongoing reliability and validity studies. Additionally, the data have clearly demonstrated the need to computerize its implementation.

Future Plans—The current OTCFA is being revised and preliminary versions are expected to be available for clinical use in 1989. Additionally, two phases of computerizing the assessment are being planned, including reliability and validating studies specific to computerized implementation.

A New Arm Ergometer for Disabled Persons

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Sponsors: *General Research Fund, Concordia University; Employment and Immigration Canada*

Purpose—The overall objective of this collaborative research is to investigate the effects of regular exercise on the health, physical condition, life expectancy, and social status of physically disabled persons. The immediate objective of this project is to develop and investigate new exercise devices and modalities specifically designed for disabled individuals. The development of exercise equipment for disabled persons should provide members of this population with appropriate and convenient means for regular, vigorous physical exercise and all associated beneficial effects.

Progress—At this time, a highly versatile ergometer has been developed. Unlike traditional devices which employ frictional or electrical braking mechanisms, the new ergometer uses a pair of viscous dampers for resistance. Each crank functions independently and exercise is performed by overcoming the viscosity of a very viscous substance (Dow Corning 200 fluid, 100.00 CS) which is contained in a sealed unit, between a fixed and a rotary plate. The resistance which varies between 60 and 165 W at 60 RPM is controlled by adjusting the distance between the fixed and rotary (crank) plates.

Preliminary Results—The device is a functional, valid, and reliable arm ergometer. Unlike traditional bicycle ergometers, the viscous damper ergometer is silent, has essentially no inertia, and may be used in any plane of motion from vertical to horizontal. The silent characteristic of this device makes it particularly suitable for home or hospital exercise programs. Independent arm exercise without inertia requires the user to drive each crank through the entire 360 degree range thus exercising constantly rather than intermittently cranking and "coasting." The lack of inertia makes the machine very safe since the cranks simply stop, should the users accidentally lose their grip on the machine. The viscous damper arm ergometer is a safe, silent, and reliable exercise machine specifically designed for physically disabled individuals.

Future Plans—The specific effects of exercise training in disabled persons using the viscous damper ergometer will be the subject of future research.

Biomechanical Measurements for Quantitative Assessment and Diagnosis of Dysphagia

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Sponsor: *Edwin Shaw Hospital*

Purpose—Dysphagia is a swallowing disorder resulting from neurological impairment and presents a major problem in the comprehensive rehabilitation of patients with stroke and other head injuries. Dysphagia often leads to several clinical problems such as aspiration, dehydration, and inadequate nutrition. Identification of the patient at-risk of aspiration is important from a clinical stand point. Swallowing generally involves the oral phase, the pharyngeal phase, and the esophageal phase. We are developing procedures for quantitative assessment and diagnosis of dysphagia involving the oral and pharyngeal phases.

Progress—We have identified and developed techniques to measure several biomechanical parameters which aid in the quantitative assessment of the oral musculature in dysphagia. These parameters include: 1) lip closure pressure; 2) lip interface shear force; 3) tongue thrust in forward, backward, and the two lateral directions; and, 4) swallow pressure.

For the quantification of the pharyngeal phase, we placed two ultra-miniature accelerometers on the outside of the throat. In addition, we monitored the swallow pressure with a catheter placed at the base of the tongue and connected to a pressure transducer. We measured acceleration and swallow pressure simultaneously in both the normal subjects and the dysphagia patients.

Preliminary Results—We have found statistically significant differences in the above parameters measured in normal and dysphagia patients. The first two parameters characterize the strength of the cheek muscles and the last two parameters characterize the tongue thrust. In current clinical practice, the strength of the oral musculature is assessed using tongue depressors and "lollipops." Monitoring the biomechanical parameters devised in the present investigation can aid the physician to objectively assess the recovery of the dysphagic patient.

In normal individuals there was no time lag between the appearance of the pressure wave and the appearance of the acceleration wave characteristic of swallowing. In patients with loss of coordination of the swallowing mechanism, we found significant lag times between the acceleration and pressure waveforms. Also, the acceleration waveform can reveal the coordination of the pharyngeal muscle contraction. Accelerometry results correlated well with clinical findings.

Implications—The biomechanical parameters identified and the measurement techniques developed in this study can be used for quantitative evaluation of the patient and for patient training to speed up the recovery process.

In current rehabilitation practice, the pharyngeal phase and coordination are assessed using video-fluoroscopy (radiography) which is often very expensive. Our results on the dysphagia patients were consistent with the video-fluorography findings. Acceleration, when measured simultaneously with the swallow pressure measurement, gives a quantitative picture of the coordination of the swallowing mechanism, and can be used in the diagnosis of dysphagia. However, a study on a larger population of patients is necessary.

Publications Resulting from This Research

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Back Analysis System

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—In 1984, we began to explore the possibility of using our median frequency technique, along with measurements of condition velocity, to assess the performance and interaction of the muscles in the trunk. One goal of this research was to develop a reliable screening method for distinguishing between the performance of trunk muscles in individuals with and without back disorders. To ensure accurate assessment of back performance, many individual muscle groups must be monitored.

Progress—A special restraining device that reliably stabilized the trunk, was designed to assure that the muscle activity observed is actually associated with the flexion and extension torques being monitored. Considerable effort was made to design the restraint apparatus so that the individual's pelvis could be immobilized for at least one hour without discomfort.

Our first postural restraint apparatus was constructed from a commercially available hexagonal tubing system used in many hospitals. The subject was secured in the apparatus, using contoured front and rear pads positioned at hip level. Forces produced during isometric contractions of the back muscles were measured with force transducers attached to a nylon harness positioned across the shoulder region of the back. These forces were displayed as visual feedback to the subject to help them maintain the desired level of muscle contraction. During each contraction, an array of six active surface electrodes attached to the back muscles monitored the resulting myoelectric activity. The back performance of over 100 subjects has been assessed using this technique.

Preliminary Results—Based on the encouraging results of these preliminary experiments with the trunk analysis system, a portable system was designed that can be transported for use outside the laboratory. In addition to its portability, the new system incorporates design features to stabilize the pelvis, upgrade the visual feedback display, and automate data collection. Pelvic stability has been achieved using a semi-rigid plastic shell that envelops the hip region. This shell produces an even pressure distribution and can immobilize the subject in a secure, yet comfortable posture. A series of shell sizes will be fabricated to accommodate a range of body types. An IBM-PC computer system forms the heart of the portable trunk analysis system. The computer controls up to 10 myoelectric signal-processing channels and a separate video display for force feedback to the subject. A menu-driven software package allows the experimenter to perform an automatic sequence of data acquisition and store the information on a floppy disk. This portable system will greatly facilitate the collection of trunk performance data.

Computer-Assisted Driver Assessment System

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Purpose—The overall objective of the Computer-Assisted Driver Assessment System (CADAS) project is to provide an objective quantitative assessment of a disabled person's physiological capabilities for driving. Quantitative data are gathered on range of motion, functional strength, and tracking simulator performance. By providing this information, the CADAS aids a driving evaluator in determining whether a disabled person can drive a vehicle and, if there is sufficient potential driving capability, in determining what vehicle modifications are necessary.

Progress—The Computer-Assisted Driver Assessment System comprises three major subsystems and a controlling computer. Software in the C programming language records client personal information and controls, and takes data from the three subsystems: the motion analyzer, the functional strength analyzer, and the tracking simulator. The modular menu-driven program also calibrates devices, guides assessment, manipulates and records data, and prints reports.

The motion analyzer has an extendable wand which is articulated in two planes. Wand length and angles in these two planes are detected by digital encoders. The system computer determines the spherical coordinates of the wand tip by counting digital pulses from the three encoders. The computer presents a menu of up to 49 predefined points for characterization of client and wheelchair. The CADAS software produces a set of data and graphs that can be used by driver evaluator, driver educator, and vehicle modifier.

The functional strength analyzer is a steering wheel mounted rigidly on a shaft instrumented with strain gauges. The steering wheel can be positioned in a variety of configurations. The strength test using the analyzer measures the static force applied to the steering wheel at various angles of tilt or to simulated hand controls. The associated software provides menus to record data in a standard format.

The tracking simulator is a device developed at the Center to evaluate ability to track a target visually while using an assistive driving device. It can be configured to use several types of brake/accelerator and steering controls. The system computer generates a moving target on a video monitor and displays the client's response according to the position of the controls. The result of the test is a set of measures of how well the client can track a target with different controls.

Results—Two systems using the IBM PC/XT microcomputer are operational. One system is located in the service-delivery area of the Center. Another system is part of a Mobile Assessment Laboratory equipped to perform pre-assessments of driving capabilities.

Future Plans/Implications—Data from the system have been used to explore the feasibility of an expert system to assist selection of driving controls and systems. Data from the motion analyzer have also been used to investigate graphical methods of selection. Ultimately, quantitative assessment information obtained from the CADAS will be used for comparison with a resident database of assistive driving devices. From this comparison the computer will recommend devices to fit a client's needs.

Publications Resulting from This Research

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A Systems Approach to Assessing Driving Skills Among Disabled Individuals. Gouvier WD, Schweitzer JR, Horton CR, Maxfield M, Shipp M, Seaman RL, Hale PN Jr, *Rehabil Educ* (in press).

Development of a Driver Assessment Protocol for the Traumatic Brain Injured. Shipp MK, Seaman RL, Hale PN Jr, *Proceedings of the Quinquennial Road Safety Congress of the Belgian Road Safety Institute* (in press).

Small-Scale Vehicle for Driver Assessment/Evaluation and Training

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Purpose—The goal of the Small-Scale Vehicle (SSV) project is to provide a cost-effective alternative to assessment/evaluation and training of disabled potential drivers. By providing a low-threat, but realistic driving environment, the SSV facilitates evaluation of driving capabilities, familiarization with assistive devices, and training on device use, vehicle operation, and driving behavior.

Progress—The SSV is an electric golf car which has been extensively modified to incorporate a variety of control, safety, and instrumentation features. Although much smaller than a full-size vehicle, the SSV offers a high degree of realism in terms of methods of steering and control, four-wheel design, and seating position. Its design permits the assessment and training of clients with a wide range of disabilities.

The steering system includes an adjustable steering column that allows the steering wheel to be positioned to meet the needs of the client. The system will accept any standard adaptive steering device.

The brake/accelerator functions are performed with the use of electronic modules or commercially-available adaptive controls, as appropriate. Modules have been built to simulate the motions and efforts required to operate push-pull hand controls, push-right angle hand controls and servo-assisted push-pull and side-to-side controls. In addition, a floor-mounted push-pull quad control, a push-right angle hand control, and a left-foot accelerator can be installed. Standard brake and accelerator pedals are also operative, with the brake system modified to require reduced effort. An added independent auxiliary braking system is for use by the evaluator and as a parking brake.

The seating system consists of automotive high-back bucket seats with restraint systems for the client and instructor. Over-all safety features include a roll bar, warning lights and buzzers, fire extinguisher, circuit breakers, and drive motor cut-off switches.

A small-scale driving course is used for operation of the SSV. By driving the course under driver-evaluator supervision, the operator experiences dynamic maneuvering challenges. The driver-evaluator is able to determine effects of vehicle dynamics on driver performance in a controlled environment. This course requires about one-fourth the area of an equivalent full-scale course.

Results—The SSV has proved to be a reliable, cost-effective, and meaningful approach to assessment/evaluation of the disabled driver.

Future Plans/Implications—The SSV costs much less to purchase, operate, and maintain than full-size vehicles having the same assistive device capabilities. Space to house and to operate the SSV is also much less. In some cases, on-the-road assessment/evaluation is completely eliminated, further reducing the need for a full-size vehicle.

Publications Resulting from This Research

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Mobile Assessment Laboratory

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The goal of developing a Mobile Assessment Laboratory (MAL) is to provide a mobile facility for pre-assessment of disabled persons' capabilities for driving. The ability to deliver this service at sites convenient to potential drivers makes evaluation for driving more readily available to a group who may not be able to come to an evaluation center because of financial or scheduling reasons.

Progress—The MAL is a Collins "Omni Baron" window van on a Ford 350 chassis with a 138-inch wheel base. It is equipped with power steering, power brakes, air conditioning, automatic transmission, roof-mounted 110-volt air conditioning and heating unit, and a Collins rear-mounted hydraulic wheelchair lift. Behind the driver's seat there is a space of 160 inches × 75 inches × 74 inches high for pre-assessment procedures. The space contains a Computer-Assisted Driver Assessment System with motion analyzer, functional strength analyzer, and tracking simulator. There is also an adjustable-height table to support equipment and supplies for hearing, vision, and psychometric testing. Only minor modifications in standard equipment layout and testing procedures were required for use in the mobile facility.

The MAL can be taken to areas far from rehabilitation centers to perform driver pre-assessments. The unit can be powered by a gasoline-powered portable generator at sites without adequate power connections. The entire MAL evaluation can be carried out by two professionals: a driver-evaluator and an assistant. One to five clients can be served per day depending on the extent of evaluation procedures necessary, and distance traveled that day. In addition to its providing greater client accessibility to driver evaluation, it is anticipated that it will offer substantial savings to driving candidates and their funding sources. By facilitating the overall assessment process, it has the potential to restore or to initiate independent driving in a cost-effective manner.

Results—The MAL has expanded the capabilities of the Center in several ways. The unit has traveled to ten different states throughout the country for workshops, conferences, and driver pre-assessments. It has become a part of the Center service delivery system supporting the Louisiana Division of Rehabilitation Services.

Future Plans/Implications—MAL equipment and procedures will continue to be improved when user feedback indicates. Its most appropriate use in different state systems will be investigated. It is anticipated that other types of assessments will also be feasible in the Mobile Assessment Laboratory.

Publications Resulting from This Research

A Mobile Assessment Laboratory for Evaluating the Driving Skills of Disabled Individuals. Horton CR, Shipp MK, Nilsen K, *Proceedings of the 10th Annual RESNA Conference,* San Jose, CA, 7:71-73, 1987.

Psychometric and Performance Predictors of Driving Ability

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of studying psychometric and performance predictors is to develop an accurate and efficient battery of assessment/evaluation tests for determining the driving ability of a disabled person.

Progress—The predictive capability of eight standard cognitive tests and two Center-developed performance tests were studied. The cognitive tests were Wechsler's Adult Intelligence Scale (WAIS), WPS Symbol-Digit, Halstead-Reitan Trail Making, Diller-Yishay Cancellation, Cognitive Rehabilitation Test (Visual React and Visual Search), Driver Performance Test (DPT), Baylor Adult Visual Perception Test, and Motor-Free Visual Perception Test (MVPT). The Center's two-dimensional tracking simulator with its pursuit tracking tasks and Small-Scale Vehicle (SSV) were also included in the expanded battery of tests administered to subjects. Error scores from the tracking tasks and driving performance scores on the SSV were considered as potential predictors of driving ability. The criterion measure in the study was the subject's ability to drive a full-size vehicle on a closed driving course. Efforts required to control the tracking simulator, the SSV, and the full-size vehicle were similar. Volunteer subjects were assigned to three groups. There were 10 traumatic-brain-injured, 7 spinal-cord-injured, and 8 non-disabled subjects in the study. With few exceptions, all tests were given to all subjects.

Results—Results of various statistical analyses indicated that an accurate prediction of driving ability can be made from a small number of tests of the candidate driver. Most results generalize across spinal-cord-injured, traumatic-brain-injured, and non-disabled persons. The strongest predictors were the Driver Performance Test, the oral WPS Symbol-Digit Test, and SSV performance. It also appears that the oral WPS Symbol-Digit, the Driver Performance Test, and the Visual React task of the Cognitive Rehabilitation Test were good discriminators of cognitive abilities among the groups tested. The findings support the feasibility of using a simple test battery to indicate which driver candidates are ready for in-vehicle assessment.

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Back Assessment of Athletes from a Varsity Crew Team

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Purpose—This project was initiated to supplement a similar study of the myoelectric assessment of back muscles in control subjects and patients with chronic back pain. The preliminary findings from that study indicate that the fatigue behavior of back muscles is closely related to the load exerted by the back muscles; to the specific muscle group of spinal level tested; and to the presence or absence of a history of chronic back pain disorder. In addition, asymmetries in muscle endurance capacity and activation were present in many subjects; some with and without a history of back pain. Since these findings suggest an association among muscle imbalances, muscle conditioning, and the presence or absence of chronic back pain, we conducted a supplementary study to clarify this relationship.

Progress—We specifically targeted our study to accomplished oarsmen because they have a high level of back muscle conditioning and, as a group, they have a high incidence of lower back pain. To address the issue of muscle asymmetries, we tested only "sweep" oarsmen because they can be further classified as port or starboard rowers.

Twenty-four men from the Boston University Varsity Crew Team participated in the study and have completed the first phase of testing. This series of tests was conducted in the same back restraining device previously described for patients and control subjects. The protocol was abridged to include a maximal voluntary contraction, a variable force contraction, a sustained contraction at 80 percent MVC, and periodic short-duration contractions to monitor muscle recovery from fatigue. The myoelectric signals detected from the 6 bilateral lower back sites were recorded on FM tape for eventual processing and analysis using the IBM/MFM. All subjects were given a brief physical examination to record anthropometrics and measure spinal flexibility. A questionnaire was developed to obtain a training and medical history of each subject's lower back.

Future Plans—A second repeat test is planned for the latter part of the training season in order to correlate changes in muscle conditioning and back pain with the myoelectric signal data. When completed, it is hoped that this information will be of use to the individual athletes and their coach as an objective measure for designing and reassessing training procedures.

The Development, Production and Assessment of Movement Training and Assessment Systems Using Microcomputers

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Sponsor: *Scottish Home and Health Department*

Purpose—A need has existed for some time for a means of quantifying many of the activities used in occupational therapy. In 1983, the Department of Trade and Industry supplied BBC Model 'B' microcomputers to a number of occupational therapy departments throughout the country. The purpose of this project is to investigate the possibilities of a microcomputer-based system for the exercising and assessment of upper limb movements. Peripheral devices are being developed to provide variable calibrated resistance to specific upper limb movements. These devices are to be interfaced to the computer and will use software to encourage patients' motivation, provide data collection, and automatic data analysis. Two centers are involved allowing for a multi-disciplinary approach. The software is being developed at the Microcomputer Centre, Dundee University, and the mechanical peripherals at the Southern General Hospital, Glasgow. The Dundee group is funded for one year, the Glasgow group for two years.

Progress—After much background research, it was decided to concentrate initially on the movements of the forearm and wrist, since equipment already existed in most departments for this (usually in the form of a wire twisting device with an array of interchangeable grip handles). A study was made of local units employing the wire twister so that advantages and disadvantages of the device could be identified. An assessment was made of software already in use in rehabilitation and also that available commercially.

Methods for providing a controlled resistance were investigated and prototypes employing these types of resistance were made. The types involved were spring, viscosity, and friction brake. They were assessed by therapists experienced in upper limb therapy. A final prototype using viscosity was built as a result of this. Meanwhile, software was written that related direction of movement of the peripheral device to movement on the screen. The program produced required the therapist to match it to the patient's needs.

The next step was to consult local experienced therapists in order to assess the grip handles. The software was improved to provide a useful scoring system and a means of collecting data useful for patient assessment.

Isometric devices have been investigated for both individual finger and gross hand grip. For the elbow and shoulder, the possibility of devices attached directly to the body was investigated in order to eliminate influences of "trick movements." As an alternative to this, a method for attaching special handles to the wrist-exercising equipment was also investigated.

Preliminary Results—Research over the past year has produced a prototype for wrist exercising, possibilities for devices for trigger and gross hand grip, and devices for the elbow and shoulder. Software research produced an activity-related program that was motivational to a wide range of patients.

Assessment of the prototype and its handles has produced improvements to the grip handles currently in use and allowed additional ones to be designed.

Future Plans—Further research will involve development of devices for rehabilitation of the elbow and shoulder. Clinical trials will be performed on the equipment already developed and its software. Finally, a commercial manufacturer will be sought for any successful package produced.

The Long-Term Effects on Gait of Ankle Arthrodesis

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Purpose—A prototype version of the VICON (Oxford metrics) movement analysis system has been installed in the Gait Laboratory at Aberdeen Royal Infirmary and is combined with a force platform for the assessment of gait in studies involving cerebral palsy children and patients who have an ankle arthrodesis.

Development, Production and Assessment of Movement Training and Assessment Systems Using Microcomputers

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Purpose—This project is an extension of a major project into the use of Microcomputers in Occupational Therapy, and is concentrating on the particular problems of upper limb rehabilitation. Software is being developed to encourage, monitor, and assess clients' abilities to manipulate their wrist and hand—in particular the movements of flexion, extension, supination, and pronation. This work will also be expanded to include other upper limb and other physical movements which are necessary for the rehabilitation of injured limbs.

IX. Biomechanics

A. Bone and Joint Studies

Biomechanics of Patellofemoral Joint Disorders

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Purpose—The force systems acting on the patella are considered to have strong correlation with patella disorders such as chondromalacia and subsequent osteoarthritis. The abnormal stress distribution in this joint is frequently caused by angular and torsional deformities of the femur.

Clinically, one sees fixed internal rotational deformities of the femur often caused by contracture of the hip rotators and by torsion of the femur. To correct this deformity, a rotational supracondylar osteotomy is often performed. This procedure, however, alters the mechanics of the patellofemoral joint, since the rotary position of the femur is corrected, but the surrounding musculature remains unchanged.

This study presents an *in vitro* and *in vivo* model to study the biomechanics of patellofemoral disorders. The objective of the *in vitro* study is to quantitatively assess the biomechanical characteristics of the patellofemoral joint under various degrees of fixed rotational deformity. A special apparatus for a human model was designed to be used in conjunction with an Instron material testing system. Ten human cadaver legs at only one specimen per week will be tested on account of the lengthy recovery period between each test. The specific data to be obtained from this study are maximum contact pressure distribution on the articular surface of the patellofemoral joint and the load relaxation behavior of the patella complex at fixed rotational deformities ranging from minus 30 degrees to plus 30 degrees at 15 degree increments. The whole procedure will be repeated at knee flexion angles at 0, 30, 60 and 90 degrees. In the *in vivo* study, we will mimic the rotational deformity of the femur on the left lower extremity and the right side will be used as a control. Four groups of skeletally mature rabbits (rotational deformities: minus 30, minus 15, plus or minus15, plus or minus 30 degrees) for three time intervals (6, 12 and 26 weeks) will be evaluated with five rabbits in each group. Thereafter, the rabbits will be sacrificed and the time-and-history-dependent behavior of the articular cartilage in the patellofemoral joint will be biomechanically characterized, using an indenter specifically designed for this study. Because of the nondestructive nature of the indentation tests, the specimens will be divided into two groups after biomechanical evaluations. One group consists of three specimens that are to be evaluated for collagen and proteoglycon content and the other group of the remaining two specimens will be used for histologic evaluations. This data can aid surgeons to prevent adverse consequences such as chondromalacia patella resulting from rotational deformities of the femur.

Mechanism of Torque Generation: Implications for Rehabilitation of Skeletal Muscle

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Purpose/Progress—We have extended the previous studies on the mechanism of knee torque generation to include the contribution of the hip. By repeating the sarcomere length versus joint angle relationship of the hip, we developed a model which describes muscle properties (sarcomere length, force, and torque produced) at any arbitrary combination of knee and hip angles. This is the first model of muscle-joint interaction which includes details of sarcomere length and joint kinematics.

Results—Using the model to predict the action of the semitendinosus (ST) during normal movement, we have shown that the ST probably does not act as a knee flexor during physiological movements, but rather acts as a "strut" to transmit the force generated by knee extensors into a hip extension moment.

We were also able to determine the relative contributions of muscle maximum tetanic tension and moment arms to torque generated at the knee joint.

Implications—Muscle force was much more important, implying that changes in muscle force can dramatically alter joint moments. These results may have significant implications in surgery involving tendon transfer.

Publications Resulting from This Research

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Study of Bone Structural Response to Altered Loading

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Purpose—The objective of this research is the study of mechanically-induced adaptive bone response with focus upon development of patient-specific, analytic, predictive models and noninvasive imaging techniques. Three-dimensional finite element models automatically generated from CT scan data are used to predict bone remodeling along principal stress direction, according to Wolff's Law. Theoretical results are compared with actual bone remodeling obtained from histology.

Progress—A two-dimensional finite element analysis indicated core drillings in a canine femur would cause altered principal stress directions and result in bone remodeling. Such drillings were performed. The results were monitored for 9 months with computer tomography (CT) scans taken in the coronal plane, and the trabecular orientations were determined from the data. Histology of the retrieved hips established the actual remodeling, permitting evaluation of our finite element predictions and our noninvasive histomorphometry technique.

To determine the 3-dimensional *in vivo* stress distribution, digital image processing software was developed. The software automatically extracts bone geometry, density, and microstructural orientation from the CT scan. To create the finite element model, 8-noded "brick" elements are automatically generated according to the bone geometry. Mesh density is user-specified. The elastic modulus is variable throughout the model and is determined by using quantitative computed tomography and a density-modulus relationship. Additional software developed in this study removes the beam hardening error from CT scan data. The method does not require the original projection data.

The CT scan image processing software for bone contour extraction and microstructural identification was tested *in vitro* using excised vertebrae. Trabecular spacing, area fraction of bone, and orientation angle were calculated with this software and compared to values obtained using thresholded CT scans.

Subject-specific, 3-dimensional finite element models of the femur were generated with the automated modeling method, and convergence of the numerical analysis was verified. To determine the effect of isotropic modeling of the mechanical properties, a transversely anisotropic model was created using the measured trabecular orientations.

Results—Comparison of the image processing results for the vertebrae with calculations made from histologic sections verified that the enhanced imaging is less sensitive to display setting than thresholding. Consequently, the new method significantly improves the accuracy of calculated trabecular spacing and area fraction of bone. The automated finite element modeling technique predicted stresses consistent with those reported in the literature. The beam hardening correction of the CT scan data prior to material modeling was successful in reducing inaccuracy from this source. This procedure was necessary because the CT scans were taken in the coronal plane, which causes streak artifact and significant beam hardening errors.

Examination of the retrieved hips revealed densification of cancellous bone surrounding the core drillings. Comparison of the measured trabecular orientations with those predicted by the finite element model did not strongly support the stress-morphology relationship. The mid-plane cross section of the femur had the highest correlation between trabecular orientation and maximum normal stress direction ($r^2 = 0.56$). The trabecular orientations predicted with anisotropic and isotropic models differed by less than 10 degrees, indicating that isotropic modeling is sufficient for predicting trabecular orientation.

Future Plans/Implications—Results of this study will be applied to study patient-specific fracture risk and prosthesis design. The automated finite element modeling technique also can be adapted to model other tissues and objects which can undergo CT scanning. It is currently being used to evaluate carbon hip surface replacement.

Publications Resulting from This Research

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Load Bearing Characteristics of the Wrist with Intercarpal Arthrodesis

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A502-RA)*

Purpose—Selective intercarpal arthrodesis has become an accepted method for treating wrist degenerative disorders, carpal ligamentous instability, and Kienbock's disease. With any fusion, motion lost in the arthodesed joints is usually shifted to adjacent joints and may cause abnormal loading in these joints. An increased load may lead to accelerated degenerative arthritis. The specific objective of this study is to define the changes in load bearing characteristics that occur with selective intercarpal arthrodesis.

Progress—Our laboratory has successfully completed three phases of tests on the load bearing characteristics of normal wrists, wrists with simulated scaphoid fracture, and those with simulated ligamentous instability. These studies have formed the basis for our current study. We have performed experiments on six fresh human cadaveric wrists in the normal state and following a simulated scaphoid-trapezoid-trapezium fusion. The data is currently being analyzed.

Publications Resulting from This Research

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Dynamic Loading of the Lumbar Spine

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Purpose—Our objective was to characterize the static and dynamic load-sharing capability of the normal and degenerated lumbar spine unit. Analysis of the results will focus on the: 1) interdependence between disc and vertebral body properties; 2) degenerative conditions which compromise the normal joint function; 3) development of clinical assessment techniques for predicting the mechanical condition of the human lumbar spine; and, 4) role of mechanical dysfunction in chronic low back and sciatic pain. Based on these results, at-risk criteria will be developed for the management and prevention of low back disorders.

Progress—Both *in vivo* animal studies and *in vitro* cadaveric and anatomical studies have been performed. The *in vitro* studies document the distribution of bone density and strength within the vertebral body, and the compressive creep and fatigue response of the normal and degenerated intact human lumbar motion segments (vertebral body-disc-vertebral body unit). *In vivo* creep-relaxation studies using a pig model assessed the mechanical behavior of normal and surgically-injured (chemonucleolysis and nucleotomy) discs under physiological loading conditions. A predictive risk was then developed, using dual photon absorptiometry (DPA) measures of bone density. These results have also been used to develop design criteria for a prototype vertebral prosthesis.

Results—*In vitro* studies of the normal and degenerated lumbar spine unit have provided insight into the interrelationships between discs and vertebral bodies. By assessing the mechanical behavior of various anatomical regions within the vertebral centrum, we confirmed that an interdependence of disc and vertebral body properties exists. Predictive models for the type and risk for vertebral fracture were subsequently developed, based upon clinical measures of bone density (DPA). These models may be used to evaluate the fitness of an individual for a given task.

Preliminary results from animal experiments indicate that the stiffness and deformation characteristics of the surgically injured disc are significantly altered. Acute chemonucleolysis and complete nucleotomy produced a 25 percent reduction in stiffness and an increased rate of creep or flow under physiological loading conditions. These results corresponded to changes found in age-related degenerative conditions observed in human lumbar intervertebral discs. We noted that normal respiration had a significant "conditioning" effect on the normal and surgically-degenerated intervertebral porcine disc, which may have important implications in terms of nutrition and development of degenerative processes.

Application of the results of these experiments to porous ingrowth components for replacement of vertebral units has led to the development of a prototype "flexible vertebral prosthesis," which mimics the normal motion and mechanical behavior of the lumbar motion segment. A flexible prosthetic design will provide for a more normal stress environment at the prosthesis-tissue interface which, while preserving a normal range of motion, may enhance subsequent bone ingrowth and healing.

Future Plans—We are developing an analytical model based upon the 3-dimensional morphology of the human spine that will provide more accurate predictions of the distribution of stresses in the vertebral unit and from which the consequences of pathological conditions and surgical interventions can be determined under a variety of complex loading conditions. Additional *in vivo* and *in vitro* mechanical tests are also being conducted to assess the role of mechanical factors in the etiology of low back pain. We plan to make prototype flexible vertebral prostheses and to perform experimental animal implantations to assess the stability and ingrowth characteristics of these devices.

Publications Resulting from This Research

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Biomechanical Modeling of the Lower Back

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Purpose—Our aim was to develop a biomechanical model of the lower back.

Methodology—A model of the lower back has been developed. The input to the model is a description of the anatomic posture of the upper trunk and limbs and the external loads applied (e.g., a person, with arms fully extended forward, holding a 10-pound weight). Using optimization techniques, the model then calculates the individual muscle forces in each of the 22 muscles that cross the lower back.

A general framework has been established to study the role of anatomy and external loading on the individual muscle force distribution. This framework has allowed us to study a wide range of isometric physical therapy exercises and their effect on individual muscle loading, as well as loading patterns of all the muscles in the lower back.

Preliminary Results—Preliminary results suggest that the optimization strategy reported in the literature and adopted in this study causes an uneven load distribution in lower back muscles. For some combinations of posture and loading, some muscles will not be activated at all, while others will carry a disproportionate load. On the basis of these results, it is clear that if a physical-therapy regimen is intended selectively to activate or relieve a given muscle or a group of muscles, one must use a biomechanical model in order to achieve the desired load distribution.

Shoulder Subluxation Measurement in the Plane of the Scapula

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Purpose—The purpose of this project is to develop an accurate shoulder subluxation measure for research application. Our method involved getting a single X-ray of the affected side in the plane of the scapula. In this plane, the two borders of the glenoid fossa appear as a single line and the gap separating the humeral head can be measured.

Progress—Subject orientation was a major area of investigation. A special chair has been constructed to position the subject prior to taking the X-ray. A palpation technique is being refined to locate specific bony landmarks on the shoulder. When they are aligned with a special light beam, the correct X-ray can then be obtained by rotating the chair.

Biomechanical Testing of a New Anterior Construct for Segmental Spinal Fusion

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Sponsor: *Howmedica*

Purpose—The use of an interbody fusion is a well-recognized technique in stabilizing a spinal segment in the surgical treatment of low-back pain. However, potential problems often arise in using this technique due to difficulty in incorporating bone grafts, resorption of the graft, a lack of anterior support, and additional morbidity in procurement of the graft. The specific objective of this study was to evaluate the mechanical stability of spinal segments under physiologic loads following implantation of a porous coated insert in the intervertebral disc space.

Progress—A total of 20 baboons were used for this study. Thirteen of these 20 baboon spines were available for biomechanical tests: 2 intact specimens, 6 specimens were from baboons that were sacrificed 6 weeks postimplantation, and 5 specimens were from animals sacrificed postimplantation. Specimens were tested to determine the segmental stiffness in flexion, lateral bending, and torsion.

Results—In general, the insert improved the stiffness of the spinal segment relative to the corresponding normal value in flexion and lateral bending. In flexion mode, the stiffness of segments with insert averaged more than 2.5 times the value for the normal intact segment, while in side bending, it was twice the normal value. There was no significant difference in segmental stiffness between the 6-week and the 12-week groups. In torsional test mode, the insert did not demonstrate significant improvement in stiffness relative to the normal value.

Studies of the Characteristics of Movements of Motor-Impaired Persons

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Sponsors: *National Health and Medical Research Council; The Channel 7 Children's Research Foundation of South Australia, Inc.*

Purpose—The aims of this project are: 1) to investigate the present functional performance of persons with physical disabilities such as athetoid cerebral palsy; 2) to study the 3-dimensional move ment patterns of the limbs, head, or trunk to determine whether, and the confidence with which, separately recognizable patterns of voluntary or involuntary movement can be detected; and, if so, 3) to investigate methods by which these movement patterns can be learned and then used within a transducing system which relies more on the relative rather than absolute movements of the user.

Progress—Initial investigations have revealed that persons with physical disabilities experience difficulties in using communication or other control devices because of positional and timing "errors" in attempting to use their present input transducers. Their intentions are apparent to a therapist or care-giver, but are not being correctly monitored by their automatic system. The problem really lies in the ineffective input transducer, not with the user.

To objectively determine the performance of subjects, we will be conducting a series of experiments using two television cameras to continuously monitor the positions of reflective markers placed on their limbs while they are executing various set tasks. A system to do this is currently being developed in-house. It has the ability to acquire and track 4 markers and to accurately determine their position at a rate of 50 observations per second. These observations can be made on-line directly, or through the analysis of video recordings of the experiments. Algorithms are being developed to analyze and plot the trajectories of these points. Whereas many researchers have investigated movements in the frequency domain, greater emphasis will be placed in this study on the time domain observations of subjects' movement patterns.

Future Plans/Implications—Experiments will be conducted to characterize the movement patterns or "signatures" of a group of children and adolescents with cerebral palsy, with emphasis on relative rather than absolute movements. This project should lead to the development of a range of smart transducers which will offer faster, more reliable access to a range of communication and control devices and systems.

Quantitative Functional Anatomy of the Human Shoulder

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Sponsor: *None Listed*

Purpose—Quantitative data on the musculoskeletal system of shoulder and arm are needed with a view to: 1) analysis of movements of shoulder girdle and arm based on arm movement registration in activities such as wheelchair driving; 2) analysis of movements of shoulder girdle and arm in activities of daily living (ADL) and vocational activities; 3) predictions of outcome of arthrodesis of the shoulder in patients with a lesion of the brachial plexus; and, 4) in general, the database can help to interpret *in vivo* human palpation data.

Progress—A palpator containing three stiff segments connected by potentiometers was developed and tested. Measuring errors are within 0.25 mm. Seven human cadavera were mounted hanging in a stiff rack. Landmarks were defined and identified by putting screws in them (bony landmarks) or fitting glass beads on them (muscular parts). Measurements were taken, and computerized. Data collection was organized in such a way that, depending on the use of the data, local or generalized coordinates can be used.

Future Plans—Some of the data will be put into a model (SPACAR) which is a dynamic version of a Finite Element Model, in order to compute movement data. Also, comparison with *in vivo* data concerning omodesis patients before and after the operation, as well as with wheelchair driving, are hitherto foreseen applications.

Use of an Impact Test in Determining Age-Related Bone Loss

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Sponsor: *None Listed*

Purpose—Radiographic examination is the most widely-used clinical method of assessing *in vivo* bone integrity. However, it is highly subjective and a substantial amount (>30 percent) of bone loss must occur before it is definitely detectable. Moreover, it exposes the patient to harmful ionizing radiation. Therefore, there is a definite need for a clinical method to assess *in vivo* bone condition that is objective, noninvasive, and reliable. The object of this study was to examine the potential of a transverse impact test as such a clinical method. In this technique, an instrumented hammer is used to produce an impact on a long bone and the response is monitored by an accelerometer.

Methodology—Transverse impact tests were conducted on 14 embalmed human tibiae. The lengths and weights of the tibiae were measured. A short duration impact was applied to the medial condyle with the instrumented hammer and the resulting vibration was monitored by the accelerometer held on the medial malleolus with an elastic strap. Both the impact and the acceleration responses were recorded on an oscilloscope. Three readings were taken per tibia so that an average velocity could be obtained.

Similar impact tests were carried out on 20 males, ranging in age from 19 to 67 years old, and 20 females, ranging in age from 21 to 58 years old. In these tests, the accelerometer elastic strap pressure was maintained in a range of 60-65 mmHg.

Readings were taken with the volunteer seated on a table, so that the popliteal region rested against the edge of the table, and the lower leg hung freely. The impact was delivered to the medial condyle where the soft tissue was judged to be the thinnest. Three readings were taken for each volunteer and an average velocity was calculated as in the case of *in vitro* testing.

Results—Data from the impact tests on the embalmed tibiae showed a statistically significant ($p<0.002$) positive correlation between the flexural wave velocity and the mass-per-unit length. This agrees with our similar findings reported before. Testing of the female volunteers revealed a statistically significant ($p<0.05$) negative correlation between the apparent wave velocity and age. The regression equation between the velocity (V) in meters per second, and the age (A) in years was: $V=482.5-3.875\ A$. Results of our impact tests on male volunteers also showed a similar trend; however, the correlation was not statistically significant.

Implications—It should be pointed out that the wave velocity measured during the transverse impact tests on *in vivo* and *in vitro* human tibiae is only the apparent velocity, and much smaller than true longitudinal wave velocity, which is approximately 3,200 to 3,300 meters per second. Our results suggest that the simple transverse impact test on human tibiae, as reported in this study, could potentially be used as a clinical diagnostic tool to screen patients with osteoporosis.

Kinematics of the Ankle and Subtalar Joint

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Sponsor: *Natural Sciences and Engineering Research Council of Canada, War Amputees of Canada*

Purpose—The objective of this research project is to develop an analytical tool (model) and technique from which the pattern of motion, occurring at the ankle and subtalar joint, can be quantitatively described. More specifically the objectives are:

1) To determine from 15 amputated lower

limbs, the direction vectors of the axis of rotation at: a) the ankle, for the movement ranging from 40 degrees plantarflexion to 20 degrees dorsiflexion and back; and, b) the subtalar joint, for the movement ranging from 10 degrees eversion to 20 degrees inversion and back. It is hypothesized that the following equations related to body kinematics can be applied to described foot and ankle movements: a) circular motion (fixed axis of rotation); b) Euler transformations (fixed center of rotation, spatial rotation); and, c) screw matrix (instantaneous center of rotation, spatial rotation and translation).

2) To determine the relationship between a noninvasive technique (using surface markers) and an invasive technique (using osseous markers) for spatial data acquisition. Once the noninvasive technique has been validated, it could be used *in vivo* to assess foot ailments, sprains, and rheumatoid feet. Therefore, physiotherapists, orthopaedic surgeons and orthotists, as well as prosthetists, would have a clinical tool for the assessment and treatment of pathological conditions of the ankle and subtalar joint. A better understanding of the kinematics of the ankle and subtalar joint could be helpful in the design of external and internal prostheses, as well as orthoses.

Results—To date, eight feet have been photographed, and three of them have been completely analyzed. The accuracy and precision of the technique was calculated to be 0.07-0.36 mm, using reference points located on a calibration device. The DLT-3D reconstruction technique revealed that neither the number of reference markers, nor the number of parameters entered in its algorithm, influenced the accuracy and precision of the technique. Motion repeatability of the limb was found to be present. For the motion at the ankle, as well as at the subtalar joint, quasi-instantaneous axes of rotation were obtained; one instantaneous axis for dorsiflexion and plantarflexion, as well as one instantaneous axis for eversion and inversion, respectively. For the ankle axes, their location was consistent for different experiments, but did not correspond with those reported in the literature (which themselves do not correspond to each other). Their orientation was also consistent with those reported. For the subtalar joint axes, their location was not consistent, while their orientation compared well to those reported.

Publications Resulting from This Research

Spatial Reconstruction Technique and Kinematic Modelling of the Ankle. Allard P, Duhaime M, Labelle H, Murphy N, Nagata SD, *Eng Med Biol* 6:31-36, 1987.

Quantitative Measures of Hand/Wrist Motions

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Sponsors: *Ohio State University Rehabilitation Engineering Center; National Institute on Disability and Rehabilitation Research*

Purpose—Most hand and wrist problems cause inflammation of the small joints of the wrist. Bone erosion, weakness of the supporting structures and imbalance of the muscle system are suspected of changing the biomechanical capacity of the metacarpophalangeal joints. We believe these changes can be quantified by observing the position and motion characteristics of the wrist. Such measurement would serve as a diagnostic tool as well as a means to monitor the extent of disability and rehabilitative progress. Thus, traditional subjective range of motion techniques may not measure the biomechanical status precisely enough and may not even focus upon the most sensitive measure.

The objective of this study is to determine whether measures of hand and wrist position and motion characteristics can serve as a means to quantify the degree of hand and wrist disability. In order to achieve such an objective, a measurement system is being developed. This device is interfaced with a software system which can quantitatively assess the motion characteristics involved in a hand and wrist action. A study will then be performed with this system which quantitatively investigates distinguishing features between the various hand and wrist problem sources and the degree of disability.

Progress—Progress to date on this project centers around the development of a hand/wrist monitor and a software program that reports deviations in hand/wrist position, velocity, and acceleration. Pilot subjects have been tested with this device and we are preparing to test a population of normal and injured subjects in the coming year.

B. Human Locomotion and Gait Training

Analysis of Gait and Postural Stability by Foot-to-Ground Force Measurements

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Sponsors: *Danish Medical Research Council; Copenhagen County Hospital Administration; Department of Mechanical Technology at the Technical University of Denmark; Hafnia-Haand Insurance Ltd.; Nordic Mutual Insurance Ltd.*

Purpose—This study was made in an attempt to provide methods which, by use of foot-to-ground forces, were able to measure gait and postural stability parameters in a form apt for clinical use. It is based on seven publications on the methods and results of gait analysis and six previously-published studies on postural stability and one study using both methods. The present study is a more extensive description of the methods applied.

Progress—The gait analysis is performed on an instrumented treadmill measuring continuous ground reaction forces on each foot separately. The advantage of the system is an extensive description of gait. The temporal factors, gait unsafety or ataxia, are determined, and by use of the Laws of Newton, the external positive and negative work is calculated for each foot. Studies of gait describe improvement after a neurosurgical intervention, as well as the influence of intake of alcohol on gait.

The postural stability is measured by calculation of the average variations in the center of the foot's pressure on a force plate. The advantage compared to previous studies is that one figure is considered a sufficient expression of the postural stability. A standard has been established for normal persons, and subsequent studies have produced information concerning the influence of various drugs and surgical interventions on postural instability.

Future Plans/Implications—The developed methods provide objective data permitting further basic studies. Applied studies should be done within the specialties of orthopedics, anesthesia, neurosurgery, neurology, and as a part of the search for effects and side-effects in pharmacology.

Development of a Posture Sensor and Sensory Biofeedback System for Use in Gait Training of the Locomotion Disabled

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Sponsor: *Japanese Ministry of Education*

Purpose—In the locomotion-disabled person, such as paraplegic or hemiplegic patients with balance deficits, information about pelvic inclination is most useful from the point of view of rehabilitation. In the present study, pelvic inclination and its time derivative in the sagittal and frontal plane, as well as transversal plane during walking, are measured by the use of an inclinometer based on the gyroscope principle. This posture sensor system is used to evaluate gait and its improvement, if any, through rehabilitation. It is also expected that information about patient posture may be gained by biofeedback through auditory tone.

Progress—All the information can be obtained from three kinds of sensors: an inclinometer and angular rate sensors are put on the pelvis by belts for measurement of absolute angular displacement of the pelvis in sagittal and frontal planes, and for measurement of angular rate in the transversal plane, respectively. Foot-switch sensors on the soles of the patient's shoes are used to detect plantar contact instants. The information is acquired and treated on-line in real-time by a 16-bit personal microcomputer via A/D converter. Several software programs were developed for measurement, data processing and graphic presentation on-screen, and then tested on the normal subjects' walks.

Preliminary Results—It was clarified by preliminary experiments that a graphic presentation shows basic characteristics of each patient's gait: for example, the walk of women who have osteoarthritis at the hip joint before and after surgical operation. Data acquired from normal subjects and patients have been characterized by the proposed check points with regard to the waveform. It has been shown that these points can reveal the differences between them.

Future Plans/Implications—It is expected to quantify the gait of each patient, for use in a rehabilitation program and to evaluate its effects. This posture sensor system will be used in combination with the sensory biofeedback system for rehabilitation use in some cases.

Publications Resulting from This Research

Measuring System of Three-Dimensional Angular Displacement of Pelvis. Ueda K, Irino I, Miyamoto H, Sakurai Y, Mori S. *Proceedings of the ICAART '88 Conference,* Montreal, 134-135, 1988.

The Clinical Application of Gait Analysis

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Sponsor: *Lothian Health Board; Spastics Society; University of Edinburgh; Women's Royal Voluntary Service; Ferranti p.l.c.*

Purpose—Our objective was to establish a biomechanical gait analysis facility for the purposes of clinical service, clinical research, and teaching.

Progress—A gait analysis facility has been established utilizing a Vicon TV-computer motion analysis system (Oxford Metrics), a force measurement platform (Kistler Instruments), and a biological telemetry system (M.I.E. Medical Research Limited). This facility will be used for a wide range of investigations relevant to the activities of an orthopaedic hospital.

A principal activity, initially, is an investigation of the use of biomechanical gait analysis for the assessment of cerebral palsied patients in a routine orthopaedic clinic. This work is being carried out in collaboration with Tayside Rehabilitation Engineering Services, Dundee, Scotland.

Walking Ability in the Stroke Patient

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—One hundred and forty-seven stroke patients were assessed to identify the critical home and community walking activities that defined their level of independence in the community. A questionnaire was used to document the customary mode of mobility (independent, supervised, assisted, wheelchair, unable) for 19 activities (7 in the home and 12 in the community).

Progress—Basic stride characteristics were measured. Muscle strength, proprioception and mobility levels were graded and given numerical scores. Each subject was placed into one of six functional walking classifications (physiological, limited household, unlimited household, severely limited community, limited community and unlimited community) based on their questionnaire responses.

ANOVA was used to test the significance of differences between groups and a stepwise discriminant analysis to identify which of the 36 variables best differentiated the six functional classifications.

Results—Mean walking velocity ranged from 6 m/min for the physiological ambulators, to 47 m/min in the unlimited community walkers, while average mobility scores progressed from 10 to 56. Strength showed a twofold increase across the walking categories, while proprioception scores were uniformly high. Significant differences existed between all functional walking groups when the mobility scores from the home and community questionnaire were combined with the subject's walking velocity ($p<.01$).

Eight key activities were identified by stepwise analysis, which significantly contributed to differentiating the functional walking categories. These included the patient's level of ambulatory independence in the home (bathroom and bedroom), two tasks involving uneven terrain (entering/exiting the home and ascending/descending curbs), three community activities (grocery stores, limited shopping center capability and unrestricted shopping center travel) and the individual's measured walking velocity.

The physiological through household categories were differentiated by the degree of independence exhibited in the two key home activities. In addition, patients in the lower groups walked slower, and their combined scores for the community activities were very low.

The two limited community categories were differentiated by the extent of their independence in handling uneven terrain and unchallenged shopping. The unlimited community ambulators were characterized by independent ambulation in all seven activities, plus attaining the faster walking velocities.

Implications—These activities can be used by the clinician to quickly identify the patient's functional level for treatment planning. Reclassification of the patients, using these key variables, resulted in 88 percent agreement with the original classification. Results of this study define the level of accomplishment that must be attained by intervention programs to successfully move a patient from household to community-level ambulation.

Quantitative Gait Analysis of Incomplete Spinal Cord Injured Patients

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Purpose—In normal gait, over 30 muscles are coordinated in one leg to take a step. Muscles are passive for most of the gait cycle, except for a critical period. To achieve coordinated ambulation with stimulation, development of an implantable, multichannel, programmable microprocessor that accounts for the patient's residual muscle power is needed. Reproduction of the normal 8-phase sequence of muscle action, however, would be technically prohibitive. To determine what compromises would be adequate, this project compared the gait characteristics of "good" and "poor" spinal cord injured (SCI) ambulators and normal controls.

Progress—The stride characteristics, lower limb muscle activity and motion, and upper limb weight bearing were determined for 24 incomplete SCI patients. The patients were divided into "good" and "poor" groups based on velocity. In each area, there were significant differences ($p<.05$) between the two groups.

Results—The "good" group ambulated four times faster than the "poor" (44 and 12 m/min, respectively). The "poor" walkers spent twice as much of the gait cycle in double limb support, while the "good" walkers spent a greater percentage in single limb support. Even though the "good" patients ambulated three times faster than the "poor" walkers, they still demonstrated velocities less than 50 percent of normal and could benefit from gait assistance by FES.

Arm support was 7 percent and 21 percent of body weight for the "good" and "poor" groups, respectively. Upper limb support was indirectly related to velocity ($r=-0.7$). High crutch forces related more to inadequate hip flexion than lack of extensor muscle activity.

Timing as well as intensity of muscle activity was critical in increasing velocity. The hip flexors of the "good" SCI patients were active earlier in pre-swing, while the EMG of the "poor" patients showed delayed onset and prolonged activity continuing into terminal swing. Both the "poor" and "good" walkers used minimal quantities of hip muscle action during pre- and initial-swing (1 percent and 2 percent of normal maximal effort, respectively). This contrasts with normal muscle flexor action of 7 percent and 6 percent of maximum EMG during pre- and initial-swing. The "good" group had significantly greater magnitude and more timely flexor muscle EMG resulting in greater and earlier hip flexion than the "poor" walkers.

The "good" group's hip flexor muscle activity was only slightly better than that of the "poor" walkers, yet they attained greater hip flexion in a more timely manner. This could be due to the cumulative effects of earlier timing and slightly greater magnitude of muscle activity, plus a faster velocity introducing greater momentum.

Publications Resulting from This Research

Quantitative Gait Analysis of Incomplete Spinal Cord Injured Patients. Perry J, Nicholson DE, Gronley JK, Barto PS, *Clin Orthop Rel Res* (in press).

Quantitative Assessment of Static and Dynamic Postural Stability in Normal Adults

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study was to examine postural stability in normal adults by identifying the position and excursion of the center of pressure (COP) during quiet standing and maximal dynamic leans.

Progress/Preliminary Results—Thirty-three normal adults, divided into three equal groups (males 20-35 years, males 55-70 years, and females 55-70 years), were tested. A piezoelectric forceplate interfaced with an Apple 2C computer was used to collect data and calculate the COP variables. This included mean COP location (in relation to the midline of the base of support), variability per second and mean deviation of the instantaneous COP from its mean location in A-P and lateral directions.

During 30 seconds of quiet standing at a sampling rate of 10 Hz, there were no significant differences in the mean location of the COP between the three groups ($p<0.05$). The mean COP location for the three groups was 0.57 cm ± 0.73 (SD) to the left of the midline of the base of support and 5.59 cm ± 1.84 (SD) anterior to the ankle axis. The COP variability/sec averaged 0.833 cm ± 0.055 (SEM) in the A-P direction and 0.515 cm ± 0.038 (SEM) in the lateral direction, indicating that postural sway in the lateral direction was 62 percent of that in the A-P direction. The COP mean deviation averaged 0.430 cm ± 0.027 (SEM) in the A-P direction and 0.262 cm ± 0.018 (SEM) in the lateral direction. The total mean COP deviation was 0.514 cm ± 0.027 (SEM), indicating that normal adults do not deviate significantly from their average center of pressure position. During maximal leaning in the A-P direction, the young males, older males, and older females were significantly different ($p<0.01$); the maximum excursion of the COP being 56.1, 41.4, and 49.0 percent of their base of support areas, respectively. Lateral maximal leans were also significantly different ($p<0.01$) among the three groups (67.7, 44.9, and 55.4 percent, respectively). Post-hoc testing identified the statistically significant difference to be between the two age groups of males.

This study identified that dynamic testing (maximal leans) was more sensitive than static testing in identifying significant differences among age groups. Dynamic testing may be the more appropriate test for objectively documenting changes in balance during a rehabilitation program.

Publications Resulting from This Research

Quantitative Assessment of Static and Dynamic Postural Stability in Normal Adults. Adams JM, Nicholson D, Perry J, Gardner E, Baker L, *Phys Ther* 67(5):747, 1987.

Clinical Gait Analysis Using the WATRACK System

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Sponsor: *NeuroMuscular Research Center, Boston University*

Purpose—The WATRACK system provides the Motion Analysis Lab with the means to perform fast and accurate measurements of human motion using an IBM-AT controlled system of two optoelectronic cameras to reconstruct the spatial position of infrared light emitting diodes (LEDs), the WATSMART system. WATRACK performs advanced processing of the spatial information and extracts the position and orientation of human body movements in its viewing volume using the TRACK software package. The overall accuracy of the system is 1 mm for translational movement and 1 degree for rotational movement.

Results—In order to make the measurements of the system clinically meaningful, the WATRACK system was modified to calculate human joint rotations in anatomic terms, thereby providing the clinician with a complete, accurate, and repeatable description of the kinematics of a given joint within hours of the time the data were collected and expressed in anatomic terms useful to physicians. Such a clinical tool will be of tremendous importance to the clinical orthopaedics community and could become the major data source for objective diagnosis of a wide range of clinical symptoms and an impartial evaluation of different treatment modalities.

The Biomechanics of Flat-Feet Running

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Sponsor: *NeuroMuscular Research Center, Boston University*

Purpose—The anatomy of the foot has a significant role in determining the nature of the biomechanical dynamic interaction between the ground and the leg. Hence, it is conceivable that a common anomaly in foot anatomy would be manifested in a characteristic biomechanical pattern. The purpose of this study was to identify such a pattern, which could serve as a measure of the clinical severity and the efficacy of a suggested orthosis prescribed for treatment.

Progress—A biomechanical study was performed that compared the ground reaction forces, measured by a force plate, generated by a group of excessive pronation ("flat-footed") subjects and a control group. The individual patterns were studied for intra-subject and inter-subject variability and for the existence of inherent/group-specific characteristics.

Results—The study found that the force trajectories had small intra-subject variability, stressing the existence of individual "signatures" of the ground reaction forces. The study further suggests that a portion of the medial-lateral force trajectory, when properly processed, is characteristic of the group. The slope of that portion of the force-trajectory was found to be twice as large for the control group compared to the patient groups not wearing their prescribed orthoses. Thus, it may be possible to use this as a biomechanical measure of flat-footedness or orthotic efficacy.

Development of a Model Clinical Gait Analysis Service

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Sponsor: *Scottish Home and Health Department*

Purpose—The objectives of this proposal has been to establish a model clinical gait analysis service for the Tayside area of Scotland and to assess the value and impact of such a facility on the clinical management of selected groups of patients.

Progress—The project commenced in August, 1985 and the following stages were completed by January, 1987: 1) the installation and configuration of a new computer system and the organization of the gait laboratory; and, 2) the implementation of our 3-D gait analysis system (incorporating VICON and Kistler force platforms) including general software for data collection and processing.

Clinical Developments. Protocols for the conduct of gait analysis tests for the three selected patient categories and their integration with routine clinical procedures have been developed. Since January 1987 a program of routine clinical testing has been conducted with the following initial experience.

Amputees. Some 40 below-knee amputees have been tested as a complement to standard techniques when optimizing the alignment of prostheses during the fitting stage of supply. Our experience suggests that these techniques permit us to detect characteristics of the stance phase of walking with the prostheses which are not detectable by subjective observation, resulting in an improved final alignment.

The general displays of gait data will now be refined to highlight the significant parameters for routine clinical implementation.

Cerebral Palsy Patients. Clinical testing of cerebral palsy patients has been directed at two areas of clinical practice: orthotic supply and surgery.

The principal consideration in orthotic supply has been the assessment of the effect of varying the ankle angle of an ankle foot orthosis (AFO) and the shape of the sole and heel configuration of footwear on the gait of the patient. A modular system of AFOs has been evolved for use during testing to overcome initial problems encountered with time-consuming traditional fabrication processes. Testing is subsequently proceeding employing this system to evaluate this area of application.

Only 15 patients have been tested prior to surgery: however, it is clear that the essential elements of such studies should include kinematic recording in conjunction with electromyography. The evaluation of the clinical value of this application will require long term follow-up of patients following surgery.

Osteoarthritic Knees. Twenty-five patients have been tested prior to surgery conducted for monocompartmental osteoarthritis of the knee. The analysis performed entails calculating the maximum mediolateral knee moment as suggested by Chadwick *et al.* (1985). Clinical verification of this application will also be dependent on the outcome of the indicated surgery.

Future Plans—The proposal is scheduled to be completed shortly. The existing program of clinical testing will be completed and displays produced suitable for the clinical presentation of the relevant data for each clinical category.

C. Other

Nuclear Magnetic Resonance (NMR), Biochemical and Biomechanical Studies of Human Foot Pads

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A466-RA)*

Purpose—Our earlier pilot studies, together with a modest prior base of work elsewhere, have shown that human plantar foot pads consist of approximately 50 percent lipid, 15 percent protein (mostly collagen), and 35 percent water. Over 95 percent of the lipid consisted of triglycerides, thus justifying use of the term "adipose tissue" for these highly specialized tissues. We further showed that the fatty acids of human foot pad triglycerides are significantly less saturated than those from all other previously investigated adipose tissues of the human body. We demonstrated that these less-saturated triglycerides possess lower viscosities than more saturated triglycerides.

A 70 kg man must accept more than 60 tons of aggregate load across these foot pads for every mile walked. We understand that jogging also involves dynamic decelerations in excess of 8 × gravity across these structures. We hypothesize that the lower viscosities of the less-saturated triglycerides improve energy dissipation by these structures. We hypothesize that multiple factors, including age, deformity, cyclic overload, metabolic disease or abnormality such as diabetes mellitus, and post-ulceration scarring alter the composition, thickness, compliance, and energy dissipation capacity of human foot pads. We know that diabetics are hospitalized more often for ulceration and infection involving the foot pads than for all other complications of diabetes put together.

We propose to continue our *in vivo* studies of human foot pads. We propose to utilize proton nuclear magnetic resonance (NMR) spectroscopy to quantitate human foot pad adipose tissues of normal people of different age brackets and of diabetics, both with clinically normal and with clinically abnormal foot pads. We propose also to perform and to correlate analyses of their biochemical composition, their sole thickness as measured by ultrasound, and the static and dynamic pressures developed in standing and walking, as measured by pedobarography.

Our subsequent goals include assessment of actual lipid turnover and of other pathophysiologic changes in these tissues as demonstrable by 13C and/or 31P NMR spectroscopy. Our ultimate objective is to better understand, then to protect, these vital tissues whose failure leads to so much pain, so much hospitalization, so much expense, and, too frequently, to amputation and disability.

Chest Wall Kinematics in Alaryngeal Speakers: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #C975-PA)*

Purpose—The intent of this pilot proposal is to investigate chest wall-respiratory function using the kinematic method: a unique, noninvasive, and more comprehensive means of studying and understanding chest wall-respiratory mechanism function in alaryngeal speakers than heretofore applied. Using magnetometers, electromagnetic transducer coils, the anteroposterior (A-P) displacement of the two-component chest wall, the rib cage (RC) and the abdomen (AB), is monitored. With movement, each component displaces volume, and because changes in the A-P diameters of the RC and AB are related linearly to the volume displaced by each respective part, together they displace a volume equal to that displaced by the lungs. Hence, using the kinematic method provides physiologically-based information regarding lung volume events with utterance in addition to information regarding the contribution of the component parts, RC and AB.

The specific objectives of this exploratory descriptive study are: 1) to elucidate chest wall kinematic function in accomplished esophageal speakers; and, 2) to determine whether chest wall kinematics differ during speech production by traditional esophageal speakers comparable in body type, age, and level of speech development, but who differ according to the presence or absence of excessive stomal noise.

Pathokinesiology of Anterior Cruciate Ligament Deficiency

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A178-3RA)*

Purpose—The objective of this project is to investigate the deviations from normal kinematics and muscle function in knees with ruptured anterior cruciate ligaments. Measurements are made using 6-degree-of-freedom goniometry and electromyography during walking and pivoting.

Progress—The knee kinematics of more than 25 individuals with uninjured knees and of 20 individuals with injured knees have been investigated. The kinematics were quantitated using helical motion analysis. The most difficult part of assessing and explaining the abnormal knee motions has been representing them in terms of anatomic variables in addition to helical motion variables. A technique has been developed which compares the motions of individual knee joints with respect to a composite normal profile and expresses any differences in anatomic variables. Our expanded database is being reanalyzed with this technique.

Results—The electromyographic (EMG) patterns of the populations of normal and injured subjects during pivoting have been compared. The results show that the gastrocnemius and hamstring patterns differ greatly. Because of the variety of EMG patterns possible, pattern analysis technique has been developed based upon Fourier spectra. All patterns in a database can be grouped according to type of linear envelope. The results of both of these developments have been presented at professional conferences and manuscripts are being prepared for publication.

Future Plans—Presently the data are being analyzed using the new techniques in order to determine differences in kinematics and muscle function between individuals with tight and loose injured knees. Also, research is continuing in order to assess the effect of corrective procedures and joint prostheses on knee kinematics and muscle function.

Publications Resulting from This Research

EMG Profiles of Knee Joint Musculature During Walking: Change Induced by Anterior Cruciate Ligament Injury. Limbird T, Shiavi R, Frazer M, Borra H, *J Orthop Res* 6:630-638, 1988.

A Model to Describe the Dynamics of Postural Sway

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—The momentary movements of the center of pressure (COP) of a standing subject, as measured by a force platform, produce a trace called a stabilogram. This trace represents the output of a complex sensorimotor system aimed at maintaining an erect posture of a human subject standing still. A series of stabilogram studies were conducted on human subjects of a young age-group (20s and early 30s) and an older age group (70s). The subjects were asked to stand still on a force plate, for a short period of time (15 seconds), while looking straight ahead as force plate readings were collected at a high sampling-rate.

Results—A statistical analysis of the momentary direction changes of the COP revealed that a simple stochastic model may be able to explain the results. The model involves an oscillatory mechanism which changes the direction, in a periodic manner, "contaminated" by a Gaussian noise. Some of the results suggest that the relative magnitude of the noise increases with age. The model is being considered as a possible tool to explain the pattern of momentary displacements, i.e., to explain the element of "random motion" observed in stabilograms.

Characterization of Normal and Pathological Postural Sway Dynamics

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Sponsors: *Technion VPR-Fund; M. Mandel Biomedical Engineering Research Fund*

Purpose—Bilateral force measurements on the supporting legs are performed to provide a new representation of postural sway based on the vector patterns of the tangential forces, the sequence of these vectors in relation to each other, and weight bearing imbalance between both legs. Additional parameters include frequency, amplitude, force activity on each foot, and asymmetry. In this study, we characterize THE postural sway of normal subjects, as well as groups of patients, including the following pathologies:. post-cerebral vascular accident (CVA) patients, post-craniocerebral injured (CCI) patients, and amputees wearing their prostheses.

Methodology—Postural sway is measured by two "Kistler" force platforms, type Z-4305, which are collaterally installed for adjacent positioning of the left and right feet during standing. The foot-ground reaction forces in the vertical, anteroposterior, and mediolateral directions are simultaneously monitored for both feet during the swaying test.

From the tracings obtained, the following are determined: 1) Relative sequence of the force vectors on both feet. The vectorial pattern of the reaction forces oscillations and their sequence in both feet in relation to each other are established directly from the traces obtained, by comparing the relative phases of the traces of the different force components for every test and each patient or subject. 2) Timing, including frequency analysis and amplitudes of waveforms of the sway oscillations. 3) Force activity, including: weight-bearing imbalance, defined in the vertical direction to express the difference between the average forces supported by each of the legs; sway total activity, to represent the vector summation of the absolute values of the horizontal force components acting on both legs; asymmetry, to express the difference in activities between the two legs. 4) Statistical analysis, for establishing the significance of the differences obtained within and between the groups studied.

Results—The results obtained disclose the reactive force patterns for each of the groups studied. Significant differences are found between the groups. The biomechanical parameters studied were correlated with the clinical parameters, and included, for the group of CCI patients, were CT-scan and MRI, as well as cognitive and behavioral measures.

A longitudinal follow-up study is also being made for the group of CVA patients.

In the group of amputees, attempts at correlating the biomechanical parameters of postural sway with the degree of alignment of the prosthesis are being made.

Future Plans/Implications—The results obtained may be used as inputs for a mechanical model of bipedal sway. Attempts ought to be made to correlate the force patterns obtained, which are often of asymmetrical nature, with the muscle activity as measured by EMG.

From the practical point of view, it is necessary to obtain more results on the mechanical parameters in order to correlate them with clinical parameters. Positive correlation may indicate usage of the sway tests for diagnostic and follow-up purposes, as well as for alignment of prostheses, in the case of amputee patients.

Publications Resulting from This Research

Postural Stability in Stroke Patients: Vectorial Expression of Asymmetry, Sway Activity and Relative Sequence of Reactive Forces. Mizrahi J, Solzi P, Ring H, Nisell R, *Med Biol Eng Comp* (in press).

Bedsore Biomechanics

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Sponsor: *The University of Akron*

Purpose—Bedsores (pressure sores) or decubitus ulcers are localized areas of cellular necrosis resulting from prolonged excessive stresses on soft tissues, and present a major problem in the comprehensive rehabilitation of spinal cord injured patients and others with paralyzing neurological diseases. The type and magnitude of stresses generated in the tissue depend on the body build, mechanical properties of the tissue, mechanical properties of the cushion, and posture. The overall goal of this investigation is to study the stress distributions developed in the tissue in individuals with various types of body build.

Progress—Pressure sores usually occur around bony prominences. A frequent site of pressure sore formation is the soft tissues of the buttock. We have developed two 2-D models of the buttock. In each of these models, PVC gel simulating the soft tissue was cast around a wooden core simulating the bone. The first model had a rounded edge core to simulate blunt bony prominence. The second model consisted of a flat circular (sharp) edge "bone" core to simulate sharp bony prominences. Each of these models was placed on a representative cushion and loaded. A grid etched on the "soft tissue" model allowed photography for calculating strains and stresses in the tissue. Cushion materials were compared in terms of the tissue-cushion interface pressure and shear stresses generated in the soft tissue.

Preliminary Results—Shear stresses generated in the model "soft tissue" were significantly larger in magnitude in the case of sharp bone core when compared to the rounded-edge model. However, the compressive stresses in the sharp-edge case were lower than the rounded-edge model. There were significant stress concentrations in the case of the sharp-edge model. Gel cushion performed better when loaded at 30 degree inclination when compared to the foam. On the other hand, foam cushions performed better under vertical loading.

Implications/Future Plans—Our preliminary results suggest that no single type of cushion can be used for the bedsore problem. There is a need to develop a composite cushion which incorporates the properties of foam (good enveloping and reduced compressive stresses) and gel (good at reducing interface and internal shear in horizontal loading). Various other types of geometries and cushion combinations should be investigated. Finite element models are needed to incorporate a variety of geometries and tissue properties. We are pursuing such studies.

Publications Resulting from This Research

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Stress Analysis of Cushion Supported Tissues with Respect to the Bedsore Problem. Candadai RS, Reddy NP, Joshi AM, *1988 Advances in Bioengineering*, ASME Winter Annual Meeting, Chicago, IL 1988.

X. Wound and Fracture Healing

Stress Analysis of Internal Fixation of Long-Bones

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Purpose—The objectives of this study are to develop models of the fracture healing process for both conservatively-treated and internally-plated long-bone fractures.

Progress—Both mathematical and experimental models of fracture healing are used to study the fracture healing process. The mathematical models utilize the finite element technique. Models of conservatively-treated long-bone fractures and plated long-bone fractures have been developed. An osteogenic index is used to predict the regions of a fracture callus which will ossify first.

Laboratory models will be used to assess a variety of plate fixation techniques. These include the use of tapered plates, the use of shortened screws at the outer screw locations, and the use of conventional plates with full length screws. A strain gauge-based torque-measuring screwdriver has been designed to monitor the insertion and removal torque of the screws which attach the fixation plate to the bone.

Results—Finite element models of plated long-bones show that slippage between the plate and the bone influences to a great extent the amount of stress shielding. Plate slippage is a direct function of screw tightness. An iterative remodeling program is currently being used to predict the changes in density distribution caused by the implantation of prosthetic implants. Preliminary models of plated long-bones will also be analyzed using this remodeling program.

Plates have been applied to phenolic tubes modeling the human radius. Strain gauges have been applied to the tubes to monitor strains during loading and unloading. Screw tightness will be determined using the strain gauge screwdriver.

Future Plans/Implications—Future plans include the use of the strain gauge-based screwdriver in surgery to compare insertion and removal torques of plated forearm fractures. It is anticipated that low values of removal torque will indicate that stress shielding is minimal and the risk of refracture will be low. The use of an iterative remodeling finite element program will allow the prediction of the change in density distribution caused by plate fixation.

Publications Resulting from This Research

Mechanisms to Alter Load Transfer Along the Diaphysis in Plated Bones (Abstract). Beaupre GS, Carter DR, *Trans Orthop Res Soc* 12:386, 1987.

Methods to Reduce Stress Shielding in Plated Bones (Abstract). Beaupre GS, Carter DR, In *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:826-828, 1987.

Short Communication: Warping of Cross Sections in the Torsion of Long-Bones with Internal Fracture Fixation Plates. Beaupre GS, Carter DR, *Orthop Res* 5:296-299, 1987.

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Incorporation of Friction Interfaces in a Nonlinear, Finite Element Model of a Plated Long-Bone (Abstract). Beaupre GS, Carter DR, Orr TE, Csongradi J, *Biomechanics: Principles and Applications*, G Bergmann, R Kolbel, A Rohlmann (Eds.), Martinus Nijhoff Publishers, 1987.

Stresses in Plated Long-Bones: The Role of Screw Tightness and Interface Slipping. Beaupre GS, Carter DR, Orr TE, Csongradi J, *J Orthop Res* 6:39-50, 1988.

Mechanical Stress and Vascular Influences on Fracture Healing (Abstract). Carter DR, Blenman PR, Beaupre GS, *Trans Orthop Res Soc* 12:99, 1987.

Correlations Between Mechanical Stress History and Tissue Differentiation in Initial Fracture Healing. Carter DR, Blenman PR, Beaupre GS, *J Orthop Res* (in press).

Finite Element Predictions of Long-Bone Remodeling (Abstract). Beaupre GS, Carter DR, In *Proceedings of the International Conference of the Association for the Advancement of Rehabilitation Technology*, 482-483, Montreal, Canada, 1988.

Fracture Healing and Bone Remodeling in Plated Long-Bones (Project Extension)

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Purpose—Our objectives are to continue the development and application of accurate computer models of long-bones treated with internal fracture fixation plates. We plan to extend the capabilities of our models to include a prediction of both the patterns of healing and the time course of bone remodeling, and thus provide the surgeon with clinically-relevant data which can be used to reduce the risk of refracture, delayed union and nonunion of fractured bones treated with plate fixation. In our analyses, we will implement theories for relating tissue stress histories to tissue differentiation and bone remodeling. This approach requires the superposition of multiple loading cases which may be encountered in the course of daily activities and represents an important advancement in analytic approaches to study fracture fixation.

Results from the first grant period have shown that significant differences in the amount of stress shielding are predicted with our more accurate nonlinear models in comparison to models utilized by previous investigators. This has important implications for the design and application of better fixation plates. Our models permit the examination of a number of important clinical issues including: screw tightness, number of screws, choice of plate material, plate geometry (tapered versus conventional), and the efficacy of using shortened outer screws as compared with full-length screws. The models allow all primary *in vivo* loading modes to be studied individually, including: bending in the plane of the screws with the plated side in tension (bending closed); bending in the plane of the screws with the plated side in compression (bending open); bending perpendicular to the plane of the screws; axial compression, and torsion. Through the use of nonlinear, contact-with-friction elements, these models include the effects of friction and relative motion between the screw-heads and plate and between the plate and bone. The relationships between these motions and individual screw tightness will be parametrically examined in order to model different degrees of plate/bone fixity associated with different stages of fracture healing. The effect of plate material will be analyzed by altering the input material properties to correspond to the most common plate materials in current use, i.e., stainless steel and pure titanium or titanium alloy.

Methodology—An iterative approach will be used to predict the morphology of the normal diaphysis from the bone stress history using models of an unplated bone. The daily loading history of the non-plated bone will consist of the superposition of multiple load cases. The determination of the relative contributions of various loading modes will be determined parametrically by a comparison of the predicted bone morphology with anatomic specimens. Each of the primary *in vivo* loading modes will be represented by a participation factor. These same loading histories and combinations will then be imposed on plated versions of the normal bone models. These plated bone models will then be used to predict the course of bone remodeling as a function of time for a given set of plate fixation parameters. Predictions from these models will be compared with literature results from *in vivo* animal studies. Both intact and osteotomized bones will be modeled. For the osteotomy models, the patterns of fracture healing will be examined in terms of a newly-developed theory which relates tissue differentiation to the local stress (strain) history.

Presently-used clinical techniques aimed at reducing the amount of stress shielding will be evaluated for their influence on the extent of predicted bone remodeling. The use of shortened outer screws will be compared with the use of full-length screws. Models incorporating tapered plates will be compared with models using conventional plates with shortened outer screws.

A companion *in vitro* testing program will be conducted to assess the efficacy of a commonly-used clinical plate application technique. Titanium alloy plates will be applied to model bones made from phenolic tubing. Axial screw force will be controlled by monitoring the insertion torque applied to each screw. Strain gauges will be mounted both on the plate and bone to measure surface strains. The *in vitro* models will be cyclically loaded and a comparison will be made of the changes in fixation stability for plated systems using shortened outer screw and for systems using full-length screws.

Electrical Stimulation of Osteogenesis Using Selected Techniques

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Purpose—This project involves the use of various selected electrical stimulation techniques for growth and repair of bone. The overall goal is to determine an effective technique to be employed in research planned to evaluate the appropriateness of electrical stimulation therapy to remobilize patients with loose prosthetic devices (trauma and irritation present), and patients with osteopenia (trauma and irritation absent). The specific aims are to: 1) define a dose response relationship in magnetic field amplitude for electromagnetic stimulation (EMS) produced by a sinusoidal waveform; 2) determine whether trauma and irritation are required with EMS produced by either a sinusoidal or a square-pulse waveform; and, 3) compare the efficacy of direct current stimulation (DCS), EMS by sinusoidal waveform, and EMS by a square-pulse waveform in the same animal model.

Progress/Methodology—Throughout this project, the tissue site selected for electrical treatment is the rabbit tibial medullary canal. The surgical intramedullary insertion and implantation of a flexible, non-metallic rod is used to produce trauma and irritation in intact tibia where indicated by experimental design. Such trauma and irritation may be required to elicit cells responsive to electrical stimulation treatment. The biological response within the medullary canal after electrical treatment is evaluated by histomorphometric quantitation of new bone formation, necrotic tissue, and selected cell types.

Originally, restraint and anesthesia of the animals, used previously by others in similar experiments, were to be employed in this research to permit daily placement of electrical devices and appliances, as well as the stimulation treatment. However, the excessive restraint, prolonged anesthesia, and consequent inactivity of the animals usually results in a loss of weight, health, and not infrequently, life. To avoid these complications, a system consisting of a jacket, tether, and swivel was developed to permit routine electrical stimulation treatment of animals with devices and appliances from any stimulation technique. It was believed that such a system would help to establish a more accurate index of the biological response to electrical stimulation with *in vivo* models. The jacket-tether-swivel system allows the animal to have freedom of movement within its cage, with access to both food and water *ad libitum*. A group of 12 animals has completed treatment with electromagnetic stimulation by a sinusoidal waveform of three different amplitudes, using the above system. The group sustained the treatment without restraint or anesthesia and there was no loss of weight, health, or life.

Preliminary Results—As a result of contact with the edges of the external electrical appliances, skin irritation was observed in several animal cases. Traumatic periosteal bone formation in these regions was not found. Intramedullary bone formation has not been indicated radiographically. The magnitude of new bone formation and necrotic tissue, if any, as well as selected cell types within the medullary canal after electromagnetic stimulation by sinusoidal waveform, is currently being evaluated by histomorphometric analysis.

Future Plans—One appliance required with electromagnetic stimulation, the coil pair, will be altered in overall size to prevent skin irritation. These new coil pairs, together with the jacket-tether-swivel system, will be employed in the remaining experiments of this research project. The use of different stimuli will be considered if electromagnetic stimulation by sinusoidal waveform is judged to be ineffective from histomorphometric analyses.

Orthotic Stabilization of Fractures of the Thoracic and Lumbar Spine

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Purpose—The purpose of this study is to investigate the biomechanical stability of spinal fractures stabilized with different orthoses and surgical constructs, used alone or in combination. The specific objectives are to: 1) measure the 3-dimensional load-displacement behavior of injured spinal segments before and after surgical stabilization; 2) measure loads exerted by spinal orthoses on the trunk in different tasks; and 3) perform a simulation study.

Methodology—To achieve the first objective, the following experimentally-created injuries will be studied: 1) burst fracture of L1 and L3; and, 2) fracture dislocation at T12-L1. The results of this *in vitro* study component will be used as input parameters to represent the mechanical properties of injured segments (with or without surgical stabilization) in the finite element model used in the simulation studies.

To achieve the second objective, measurements will be performed on the 3-point hyperextension orthosis and the molded plastic thoracolumbosacral orthosis (TLSO). The results of this *in vivo* study component will be used to define the kinetic boundary conditions at the contact areas between the orthosis and trunk in the finite element model used in the simulation studies.

The simulation study will be performed with the following objectives: 1) to estimate the extent to which the 3-point hyperextension orthosis and the molded plastic TLSO improve the load-carrying capacity of the injured spine whose ability to withstand loads has been compromised by burst fracture of L1 and L3 and fracture dislocation at T12-L1. The ability of the spine to withstand loads without causing the progression of a deformity will be estimated in a spine with a specific type of injury *without* orthotic support, and in a spine with a specific type of injury stabilized *with* a specific type of orthosis; and, 2) to estimate the segmental motion and net loads induced at the injury site and at instrumented segments when the spine is subjected to physiologic loads in a spine with a specific injury supported by an orthosis alone, in a spine with a specific injury stabilized with a surgical construct alone, and in a spine with a specific injury stabilized with a surgical construct and a postoperative orthosis. This study will use a finite element model of the spine-orthosis system to simulate the response of the spine to external loads, and will utilize the data obtained in the first and second objectives.

The long-term goal of the study is to develop rational treatment guidelines to adequately protect patients with spinal trauma during the healing process of spinal injuries, while preventing unnecessary instrumentation or bracing. Results of the proposed 3-year study will provide a rational basis to design a prospective clinical study of patients with spinal trauma to identify fractures that can be stabilized with orthoses alone, and to identify combinations of fractures and surgical constructs that may need no postoperative orthotic stabilization. Further, we expect that the results of the proposed 3-year study, combined with the results of a prospective clinical study, will identify optimum postoperative orthotic prescription for a given spinal injury stabilized with a surgical construct so as to achieve maximal stability with minimal postoperative immobilization.

Testing of Design Parameters for a Prototype Piezoelectric Internal Fixation Plate

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Purpose—Stimulation of bone healing by microampere electric currents is now a recognized form of clinical treatment. For this purpose, various devices are available that aim to improve the healing of bone in problem cases, particularly for individuals with delayed or nonunion. Typically, the stimulatory current is provided by a battery-powered device that delivers current to bone via electrodes or by an external electromagnetic device that induces currents in bone. Our purpose is to develop a novel approach to electrical stimulation of bone healing that employs microampere currents generated during physiological loading by a piezoelectric material that is incorporated as part of an internal fixation plate. Alternatively, current can be generated by external application of ultrasound to the skin over the plate. Thus the "piezoplate" will represent an implant that will not only stabilize bone, but also will provide an internal source of electrical stimulation in response to physiological loading or low level ultrasound.

Progress—To date, we have designed and tested several versions of the "piezoplate." Because initial tests showed the piezoelectric ceramics placed in direct contact with bone were not effective, we developed a device in which the piezoelectric material is sealed within the plate and all charge developed is collected and delivered to bone via electrodes. In addition, a special miniature circuit has been developed to process a charge from either mechanical loading or ultrasonic activation into a microampere DC current in the range known to stimulate osteoporosis. Additional tests are being conducted on the standard rabbit tibia model to determine whether or not AC currents at ultrasonic frequencies may also stimulate formation. During the past year, a canine model of nonunion also has been developed specifically for testing of the piezoelectric plate *in vivo*.

Results—Development so far has been achieved in three areas. First, we have identified a final design and circuitry of the piezoplate for tests in canine subjects. Second, we have concluded tentatively that rectification of currents generated is a necessary aspect of signal processing (although tests with unrectified, ultrasonic frequency currents are still in progress). Third, we have developed a suitable canine model for testing in which a 2.5 cm gap osteotomy is created in mid-radius. When fixed with a 6-hole titanium plate of stiffness equivalent to the piezoelectric plate, these defects lack approximately 5 mm of bone bridging at 12 weeks. These results are highly consistent and this will provide an excellent model for tests of the "piezoplate."

Future Plans—During the coming year, tests with the canine model are planned with a comparison of results obtained in both weightbearing and ultrasonic modes of application. Current will be delivered by two platinum cathodes in the gap and around the anode at a remote site.

Publications Resulting from This Research

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Absorbable Fixation Devices: Orthopaedic and Reconstructive Surgery: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Proposal #A940-PA)*

Purpose—The goal of this pilot study is to demonstrate that recent advances in polymer sciences, glass science, composite fabrication, and biomechanics can be synthesized into a process for the manufacture of functional absorbable fixation devices. We have demonstrated that a metal rod effectively stabilizes the osteotomy in the cat model.

Methodology—Absorbable fixation devices could replace a large portion of the metal devices which are now in use, and which often must be removed for cause (e.g., stress-shielding osteopenia, late infection, etc.). The absorbable device would dissolve slowly after the healing of the lesions, thus obviating the removal operation. The material for the implant will be a composite consisting of a polylactic acid (PLA) polymer matrix stiffened with 15 μm fibers of a phosphate glass called Metaglass (metabolizable glass). The Metaglass has better stiffness and dissolution behavior than the Ca metaphosphate glasses used by previous investigators.

Progress—We have the PLA and Metaglass fibers and are currently manufacturing dyes for the composite rod fabrication. The surgical technique has been refined on euthanized and anesthetized cats.

Future Plans—Implantation of composite rods will begin shortly. The strength of the rods will be determined by mechanical testing, and their ability to stabilize femoral osteotomies in cats will be evaluated. If this pilot study is successful, it will be followed by a request for a full scale, Type I study, to optimize the fabrication process, complete characterization of the materials and devices, and assess long-term *in vivo* effects

Enhancement of Union in Segmental Defect Fractures

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A278-RA)*

Purpose—The object of this study is to define the healing parameters of synthetic bone graft substitutes when used in a previously developed canine model of bilateral segmental defect fracture healing. These synthetic bone grafts are compared to the ideal bone graft material, autogenous cancellous bone graft. Prior work has determined that autogenous cancellous bone graft (CAN) consistently results in 100 percent solid union when used in this model. Ground autogenous and allograft bone, both cortical and cancellous, have been shown to be ineffective in uniting this segmental defect fracture.

Methodology—Multiple synthetic bone graft substitutes have been used, including calcium hydroxyapatite (CHA), tricalcium phosphate (TCP), and a combination of collagen, hydroxyapatite, and TCP. These materials were used with and without additional bone marrow aspirate. The methodology has been to perform bilateral surgery on dog radii, creating a 2-centimeter defect at the junction of the middle and distal third of the radius which is fixed with an external fixator. Periosteum is totally excised from the defect. CAN obtained from the contralateral head is used as a control. After a period of 12 or 24 weeks, the dog is sacrificed and the radius is studied for mechanical strength as well as histomorphometry. This model allows a controlled study in individual animals.

Results—This segmental model has demonstrated that CHA and TCP are ineffective alone; both improve to near 40 percent of the effectiveness of CAN when used with bone marrow aspirate. TCP resorbs about 80 percent by 6 months, leaving normal-appearing bone, while CHA remains. Collagen with CHA and TCP is near 50 percent as effective as CAN, and the material improves to 100 percent with the addition of bone marrow aspirate. Therefore, collagen plus ceramic with bone marrow aspirate can achieve union rates and bone strength that rival CAN in this segmental model. Early work has been performed with a variable external fixator that allows transfer of bone segments across this defect model. Preliminary studies show results near 100 percent effectiveness as cancellous bone graft, but technical problems occur with the transfer. No bone graft is used, but bone fills in behind the transfer segment. Further studies on frame configuration, rate of transfer, bone blood flow, and many other questions remain to be answered.

Morphologic and Ultrasonic Analysis of Normal and Ischemic Human Wounds

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Purpose—For the past 5 years, we have engaged in the investigation of deficiencies in the wound healing process in individuals with peripheral vascular disease (PVD) and diabetes mellitus (DM). We hope to identify abnormalities in the repair process which may suggest clinical interventions.

Methodology—We utilized standard incised wounds created with a Simplate II bleeding time device to produce uniform wounds on normal elderly subjects as well as patients with PVD or DM awaiting amputation. A variety of time points following wounding have been evaluated. We recently gained access to new antibodies to growth factors, including transforming growth factor (TGFB) and TGFA and platelet-derived growth factor (PDGF). We plan to study these and other growth factors in our wound model. In addition to morphological and immunochemical evaluation of the repair process, we are investigating the use of high-frequency ultrasound as a method for noninvasive evaluation of the repair process. A scanning laser acoustic microscope (SLAM) is being used for the latter studies.

Results—We have studied 40 individuals with PVD or DM and 25 normal elderly subjects. We have developed a time table for morphological and immunochemical events of epidermal repair on the lower extremities of elderly normal subjects and are using those standards for comparative studies in individuals with PVD and DM. We have also used the wound model to study the time table for various matrix proteins such as thrombospondin. We have a major interest in assessing the role of nonenzymatic glycosylation in the abnormal repair process for individuals with DM. We have succeeded in immunostaining of tissue sections with a monoclonal antibody specific for the glucitol-lysine linkage, which is the site of nonenzymatic glycosylation of proteins. We are evaluating the location of nonenzymatic glycosylation in diabetic skin, nerves, and blood vessels as well as wound tissue in a diabetic rat model. Considerable progress has been made in the use of ultrasound to assess skin and wounds.

Future Plans/Implications—We hope to be able to use our monoclonal marker for nonenzymatic glycosylation to identify specific cells, and perhaps areas in the wound matrix which may be most affected by nonenzymatic glycosylation. We also plan to evaluate normal wounds and wounds from patients with PVD and DM for the presence of a variety of growth factors as well as a time table for appearance and disappearance of those factors. Our model is also well-suited for the use of *in situ* hybridization techniques for assessment of repair parameters. We hope to identify abnormalities in the repair process by comparing normal elderly subjects with individuals with PVD and DM.

Experiments are also underway to assess the utility of high-frequency ultrasound in assessing wound maturation. It may be possible to assess abnormalities in the material properties of wounds, such as tensile strength and collagen content, as well as assessing images which may identify early evidence of wound failure.

Publications Resulting from This Research

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Orthokinetic Orthoses: Clinical Efficacy Study of Orthokinetics Treatment for Colles' Fracture Post-Immobilization Hypokinesia

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Sponsor: *Orthokinetics Research Foundation*

Purpose—This study investigated the clinical efficacy of application of orthokinetic orthoses to the upper extremities of patients with Colles' fracture post-immobilization hypokinesia of wrist motion. The orthokinetic orthoses were designed and fabricated from spandex reinforced elastic roller bandage material by the continuous foldover process described in earlier publications of the author's multidisciplinary clinical research team.

Progress—The subject had limited wrist flexion, not rehabilitated by conventional treatments. The orthokinetic treatments comprised a single-subject time-series design.

Results—The patient was an 84-year-old woman, who had sustained Colles' fracture of the left wrist in a fall 8 weeks prior to presenting at the Occupational Therapy Department of a skilled nursing facility. She had received 2 weeks of physical therapy for mobilization of her left wrist and hand. Both wrists had normal dorsiflexion. Volar flexion of the right was 40 degrees, and of the left 33 degrees; fist closure of the left hand showed a 1 cm gap. Grip strength on a Vigorimeter was 0.34 Kpa in the right, and 0.12 Kpa in the left hand. She was treated by application of orthokinetic orthoses to forearm and wrist, the treatment comprising a single-subject time-series A1-C1-A2-C2-A3-B1-A4-B2: A1 = negative control pretreatment phase; C1 = placebo phase, by application of 2 orthoses with 2 layers of plain elastic bandage (lacking an inactive field) on forearm and wrist; C2 = sham treatment phase, by application of 2 orthokinetic orthoses with 2 layers of active field and 4 layers of inactive field, placed in reverse orientation (relative to the theoretically-correct orientation designed for the orthokinesis effect). One cuff was placed on the forearm, with the active field over the wrist/long finger extensors, and the inactive field over the wrist/long finger flexors. A second cuff was placed with the active field over the dorsal aspect, and the inactive field over the volar aspect of the wrist. Control phases C1 and C2 were interspersed with nontreatment phases A2 and A3; followed by phase B1 = orthokinetics treatment phase, with the same orthokinetic orthoses as in phase C2, but rotated through 180 degrees to the theoretically-designed orientation for effecting orthokinesis: the active field of the forearm cuff over the wrist/long finger flexors, and the inactive field over the wrist/long finger extensors; the active field of the wrist cuff over the volar, and the inactive field over the dorsal aspect of the wrist. Orthokinetics treatment phase B2 was a replication of phase B1. Time-series phases A1 through B1, and phase B2, were of 60 sec duration each. Phase B1 was followed by a nontreatment phase A4 of 2.5 hours, during which the patient pursued activities of daily living. The treatments C1, C2, B1, and B2 were applied single-blind. The outcomes were recorded on 3 criterion measures: grip strength (on a Vigorimeter, in Kpa); wrist flexion (in degrees); and fist closure (gap in cm). The outcomes of the negative (nontreatment) control phases (A1, A2, and A3) were negative, as were the outcomes of the positive control phases (C1 and C2), in contrast to the positive outcomes of the orthokinetics treatment phases (B1 and B2), which resulted in fast partial remediation, with carry-over, of Colles' fracture post-immobilization hypokinesia. The changes on the 3 criterion measures—58 percent increase in grip strength, 39 percent increase in wrist flexion; and complete fist closure—were in the direction posited, and they supported internal validity and clinical validity of orthokinetics treatment for the patient's hypokinesia.

Future Plans—Future plans for the project include exploration of clinical efficacy of orthokinetic orthotics in post-immobilization hypokinesia due to fractures (e.g., scaphoid fracture); and to athletic and industrial injuries of the upper and lower extremities.

Publications Resulting from This Research

Orthokinetic Orthoses Application in Treatment of Patients with Colles' Fracture Post-Immobilization Hypokinesia: A Single Design Efficacy Study. Neeman RL, *Physiotherapy Canada* 40(5), 1988.

XI. Muscles, Ligaments, and Tendons

A. General Properties of Muscle

Motor Control in Subjects with Clinical Disorders

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Sponsor: *VA Outpatient Clinic, Boston, MA*

Purpose—Traditionally, clinicians have relied primarily on information relating to the size, number, and spatial distribution of motor units to assist them in the diagnosis of neuromuscular disorders. As the neuromuscular system is modified by disease, both muscle contraction capabilities and methods of control may change. Therefore, information relating to the manner in which motor units are controlled during muscle contraction may contribute substantially to the diagnostic power of clinical electromyographic tests. Thus this ongoing study focuses on how motor control might change in certain patient populations. The behavior of motor units in normal subjects is used as a basis for comparison of motor unit activity in neuromuscularly affected subjects. Such comparisons are expected to yield useful information that will lead to the development of procedures for aiding clinical diagnosis.

Progress—Myoelectric signals have been acquired from the first dorsal interosseous muscle of several patients with different clinical disorders. Individual motor unit information is then extracted from the detected signals by the decomposition technique. The existence of common drive and the relationship between motor unit firing rates and recruitment levels as functions of percent maximal voluntary contraction are specifically addressed and compared to normal subject population results.

Subjects with cerebellar atrophy, ulnar nerve neuropathy, and syrigomyelia have been studied. Generally, a common drive of motor units is observed. The patient afflicted with syrigomyelia appears to have a compressed range of motor unit firing rates when compared to normal subjects performing similar contractions. Further study of the data collected from these subjects and others is ongoing. In addition, the development of a specialized combined selective-concentric surface needle will allow for the combination of both temporal and morphological individual motor unit information. For both early and late recruited motor units, motor unit sizes, firing rates, and recruitment force thresholds will be known.

Automatic Analysis of Surface Electromyograms

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Sponsors: *VA Rehabilitation Research and Development Center, Palo Alto, CA; VA Career Development Program; Muscular Dystrophy Association*

Purpose—The purpose of this project is to develop accurate methods for recording and analyzing electromyogram (EMG) activity using surface (skin) electrodes. The use of noninvasive electrodes will reduce the discomfort of the EMG examination, making diagnostic evaluation and serial EMG monitoring (e.g., of response to therapy for neuromuscular disability) more feasible, particularly for children and those adults with low pain tolerance.

Methodology—Surface EMG recordings have generally been considered unsuitable for electrodiagnosis, even of superficially-situated muscles, because of the attenuation and distortion suffered by the myoelectric signals as they pass through the subcutaneous tissues and the skin. Recently, however, new types of surface electrodes have been developed that are capable of detecting the fundamental electrophysiological components of the EMG signal—the discharges of individual groups of muscle fibers known as motor-unit action potentials (MUAPs). These electrodes consist of arrays of very small (1 mm diameter), very closely-spaced (2.5 to 5.0 mm) metal contacts, or closely-spaced needles that penetrate only the outermost layer of the skin. The signals recorded by the various contacts can be combined in such a way as to accentuate the more superficial MUAPs while suppressing the deeper ones.

EMG signals will be recorded from the skin surface by an array of small contacts. Signals from adjacent contacts will be subtracted to accentuate the MUAPs. The signals will be decomposed into trains of individual MUAPs, using a modified version of our ADEMG program (a program originally developed to analyze needle-recorded EMGs). The ability to record the MUAP waveform at many points on the skin surface simultaneously will allow estimation of properties that cannot be easily measured using needle electrodes, including the size and conduction velocity of the motor unit, and the location and spatial extent of the motor endplates.

Progress—We have developed a prototype hand-held surface EMG electrode whose features include detachable heads for either flat or needle-type contact arrays, a metal shield to ground the electromyographer and suppress noise, and an on-board buffer amplifier. Two EMG signals were analyzed by the ADEMG program, and three MUAPs were identified along with their firing patterns and conduction velocities.

Future Plans—Future plans call for refinement of the prototype electrode, optimization of the analysis program, and development of algorithms for estimating motor-unit anatomical properties from multiple surface recordings. Our goal is to develop a system for whole-muscle mapping that will consist of a large electrode with many contacts, a multichannel recording system, and a multichannel analysis program.

Publications Resulting from This Research

Decomposition Analysis of the Surface Electromyogram. McGill KC, Dorfman LJ, Howard JE, Valainis EV, *IEEE 9th Annual Conference of the Engineering in Medicine and Biology Society*, 2001-2003, 1987.

Automatic Decomposition of the Electromyogram

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Purpose—A quantitative method for analyzing electromyogram (EMG) signals would provide greater objectivity, reproducibility, and diagnostic sensitivity in EMG examinations. This in turn might be expected to result in earlier and more accurate diagnosis of neuromuscular disorders, with earlier institution of specific treatment where appropriate, resulting in more favorable disease outcome with less residual disability.

We believe that it should be possible using computers and advanced signal-processing techniques, to decompose moderately complex EMG signals into their component motor-unit action potentials (MUAPs).

Methodology—We have developed a method called Automatic Decomposition Electromyography (ADEMG) which is able to decompose EMG signals recorded at up to 30 percent maximal contraction and containing up to 15 simultaneously active MUAPs. The method employs several novel signal-processing steps which include digital filtering to enhance MUAP detection, high-resolution template-matching to improve the accuracy of MUAP identification, and firing-pattern analysis to verify MUAP validity. ADEMG is fast enough (one to two minutes processing time per 10-second EMG signal) to be practical for routine clinical use. ADEMG has been licensed and is now commercially available from Nicolet Biomedical Instruments.

Progress—We are now in the process of clinically evaluating the ADEMG method. This includes the evaluation of ADEMG's performance by means of computer simulations, the collection of a database of normative MUAP properties, the analysis of patients with known or suspected neuromuscular disorders, and the investigation of EMG changes during fatigue.

Publications Resulting from This Research

Automatic Quantitative Electromyography, Muscle and Nerve. Dorfman LJ, McGill KC, *Muscle and Nerve* (in press).

Automatic Decomposition Electromyography (ADEMG): Technical and Methodologic Considerations. McGill KC, Dorfman LJ, *Computer-Aided Surface or Needle Electromyography and Expert Systems in Diagnosis*, J.E. Desmedt (Ed.), Amsterdam: Elsevier (in press).

The Myoelectric Signal Decomposition Technique

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—Myoelectric signal decomposition is a procedure for studying the individual behavior and interactions of populations of concurrently active motor units. Individual motor unit information is obtained by analyzing myoelectric signals detected by selective indwelling electrodes during muscle contraction. The procedure consists of three main parts: signal detection, acquisition, and decomposition.

Progress—Development and refinement of the motor unit analysis procedure has concentrated on increasing the speed and ease with which the analysis can be performed. Improvements have included developing alternate electrode configurations better suited for the detection of myoelectric signals of suitable complexity; signal quality monitoring during signal acquisition to ensure stable and myoelectric signals for high yield and successful decomposition; and modifications to the decomposition algorithm to reduce and improve operator interactions and maintain decomposition accuracy. Further improvements are planned involving real time data acquisition and automatic signal decomposition. Techniques for the combination of temporal information with the more classical morphological information used clinically are also being developed.

Using the signal decomposition technique, investigations into a number of interesting motor control questions are being conducted. The interdependent nature of motor unit discharges or motor unit synchronization has been demonstrated and an underlying mechanism suggested. The role of the central and peripheral nervous systems in the existence of the common drive measured for motor unit pools of individual and pairs of muscles is being investigated. The effects of aging and specific movement disorders on the methods used to control muscle contractions are being examined. Changes in motor unit behavior due to the loss of skin sensory input are being investigated. Motor unit firing behavior changes and other myoelectric changes occurring during fatigue and individual motor unit morphology as it relates to motor unit recruitment and firing rate behavior are being studied by the combination of the signal decomposition technique with the acquisition of ancillary signals.

Synchronization of Motor Unit Discharges

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—Synchronization of motor unit discharges is defined as the tendency for pairs of motor units to contract with preferred latencies relative to each other more often than would be expected if the motor units were functioning independently. A study of the interdependence of concurrently active motor units was performed.

Progress—Individual firing times of groups of concurrently active motor units during voluntary isometric contractions were obtained using the signal decomposition technique. Pairs of motor units were then chosen and cross-interval histograms were created using their firing time histories. The histograms were constructed based on the time intervals between the firing of a triggering or conditioning motor unit and the subsequent firing of the alternate or conditioned motor unit of the pair. If we assume that the motor unit pairs were operating as independent Gaussian point processes, then the histograms could be statistically analyzed to determine the existence of significant interdependence or synchronization.

The latency at which synchronization was maximum and the range of latencies that occurred over synchronization were computed. The amount of synchronization was then expressed as the average deviation of the histogram from the expected mean computed over the latency range measured in normalized units. The percentage of pairs exhibiting synchronous behavior was also calculated.

Results—Synchronization measurements of motor unit pairs studied in human first dorsal interosseous (FDI), deltoid and tibialis anterior (TA) muscles during a variety of force protocols indicate that more than 60 percent of the motor unit pairs examined exhibited synchronization. The latency of the histogram maximii were most often within ±5 ms and had an average width of about 4 ms. Long latency synchronization (histogram peaks at 10-40 ms) was also observed, but to a lesser extent. The deltoid had lower amounts of synchronization than the FDI, which in turn had lower levels than the TA. Synchronization was found to increase with the level of contraction in the deltoid and FDI. Analysis of motor units in synergist and antagonist muscle pairs revealed interdependence within, but not across, the muscles.

Implications—These results support the hypothesis that synchronization is indeed a property of most contracting muscles. The relationship between long latency values and a muscle's approximate reflex arc delay, and the increased amounts of synchronization with increased proprioceptive feedback (during physiological or fatigue-induced tremor), strongly suggests the involvement of the stretch reflex as a fundamental component cause of motor unit synchronization.

Median Frequencies of Myoelectric Signals

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Purpose—During an ongoing muscle contraction, the median frequency (MF) of a bipolar surface detected myoelectric (ME) signal progressively shifts to lower values. These spectral shifts have been related to muscle fatigue and have been used as objective dynamic indicators of the fatiguing process. The exact causes of the median frequency shifts during fatiguing contractions are still unknown, although they have been partially attributed to changes in muscle fibre conduction velocity (CV).

Other possible causes such as changes in tissue impedance, changes in the detecting electrode configuration's transfer function, and changes in motor unit firing behavior have not been suitably studied.

Progress—ME signals detected simultaneously from common muscle volumes using an indwelling needle cannula and a monopolar and bipolar surface electrode configuration propagate through different impedances. Therefore, comparisons of the median frequency of the ME signals detected via various modalities can help determine the effects of the detection methods on median frequency changes. ME signals were detected simultaneously from common tissue volume of human first dorsal interosseous (FDI) and tibialis anterior (TA) muscles using an indwelling needle cannula and a bipolar and monopolar surface electrode configuration during fatiguing, one minute long, 80 percent maximal voluntary contractions. ME signal average conduction velocity and the median frequencies of the ME signals detected with each electrode configuration were calculated.

Conduction velocity declined with an average normalized slope of 0.33. Median frequencies of cannula and monopolar surface-detected ME signals had essentially equal rates of decline of median frequency (average normalized slopes of 0.53 and 0.54 respectively), while bipolar detected ME signals had greater rates of decline of median frequency (average normalized slope of 0.73).

Results—The increased rate of decline of cannula and monopolar surface-detected ME median frequencies compared to the measured decline in CV suggests components contributing to the shifting ME spectrum which are unrelated to CV. In addition, a ME spectrum whose shifting was solely dependent on CV would result in identical normalized declines in median frequencies for both monopolar and bipolar detected signals. Therefore, the increased declines of the median frequencies of bipolar detected surface ME signals also indicate non-conduction velocity related shifts in the underlying ME phenomena accentuated by the bipolar detection configuration. These results confirm earlier work carried out at the Center which suggested that ME signal spectral shifts are not wholly dependent on CV changes and that further study of individual motor unit firing behavior during fatigue is necessary.

The common rate of decline of the median frequencies of cannula and monopolar surface detected signals suggests that the activity within the muscle is traveling through a static inter-tissue impedance to the monopolar surface detection site. Therefore, changing tissue impedance is not a likely component cause of discrepancies measured between the rates of CV and median frequency decline.

Components of Common Drive

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Purpose—The term *common drive* is used to describe the common fluctuation found, using cross-correlation analysis, in the mean firing rates of active motor units during isometric contractions. Common drive suggests that motor units of a single muscle are not controlled individually, but rather as functional units. Studies of an antagonist muscle pair, the flexor pollicis longus and the extensor pollicis longus, have also revealed the existence of common drive, with essentially no time shift among motor unit pairs chosen across the muscles. This investigation was undertaken to determine if functional commonality was a sufficient condition for the existence of common drive across a muscle pair, or if functional and mechanical linkages were required. We believe that interpretation of the results of this study will lead to a better understanding of the role of central and peripheral nervous system inputs in common drive.

Progress—A set of two experiments was performed. In the first experiment, the subject's first dorsal interossei (FDIs) pressed simultaneously against force transducers while attempting to follow two identical trapezoidal force trajectories. The force trajectories had a plateau at 30 percent of the subject's maximal voluntary contraction (MVC) level. In this case, the muscles were said to be functionally linked. In the second experiment, the subject's indices pressed against each other so that a net zero force was achieved, thus mechanically and functionally linking the muscles. The firing times of motor units active in each muscle were obtained via the decomposition procedure.

Mean firing rates of selected motor unit (MU) pairs were cross-correlated to identify common characteristics in their firing behavior. Cross-correlations were calculated for selected motor unit pairs belonging to one muscle and between MUs chosen across the right and left FDI muscles.

Results—Cross-correlation data between mean firing rates within MUs of each FDI have shown significant common drive, with peak cross-correlation values ranging from 0.4 to 0.9. In contrast, when the right and left FDIs were functionally linked, no common drive was found between the motor unit pairs chosen. This was indicated by the peak cross-correlation values which ranged from 0.2 and 0.4. When the muscles were functionally and mechanically linked, peak cross-correlation values ranging from 0.3 to 0.6 were observed. This showed the existence of some common drive across the muscles. For this case, the time of occurrence of the peak cross-correlation values was not found to be significantly different from zero seconds ($p = 0.05$).

Implications—The peak cross-correlation values obtained within the FDI muscle are in accordance with previous findings. Thus, there does exist a common input to each muscle which provides a common modulation of the firing rates of their motoneuron pools. The results obtained across the FDIs suggest that functional linkage is not a sufficient condition for the existence of across-muscle common drive. Alternatively, mechanical and functional linkage is required. This suggests the need for a proprioceptive linkage between the muscles. In conclusion, the existence of a central as well as a peripheral (proprioceptive) component is proposed to contribute to the common drive between the muscles.

Sensorimotor Interaction in Motor Control

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—This study is a continuation of previous work done at the Center, investigating the effects of topical anesthetics on the recruitment thresholds of individual motor units. Earlier results indicated that due to skin desensitization, the recruitment force levels of motor units recruited below 10 percent MVC level increase, while those of motor units recruited above 20 percent MVC decrease. These effects are noted up to 45 minutes post-anesthetic application. It was suggested that the sensory input from the skin has an excitatory effect on the small slow-twitch motor units and an inhibitory effect on the large fast-twitch motor units. This study further analyzed the earlier topical anesthetic data as well as collected and analyzed additional data.

Progress—Myoelectric signals were detected from the first dorsal interosseous muscle while subjects generated isometric trapezoidal-shaped contraction trajectories up to the 50 percent MVC level. Thereafter, the signals were decomposed into their constituent motor unit action potential trains. The recruitment force thresholds of the progressively recruited motor units, as well as their mean firing rates at the 50 percent MVC level, were determined before and at 15-minute intervals after the application of topical anesthetics for up to one hour post-application.

Results—The results substantiate the earlier observed recruitment threshold changes. In addition, a strong and stable relationship was found between a motor unit's mean firing rate at the 50 percent MVC level and its recruitment threshold; i.e., a motor unit's firing rate at the 50 percent MVC level of contraction can be predicted from its recruitment threshold, and as the recruitment thresholds change due to the effects of the anesthetic, the firing rates also change. Decreased recruitment thresholds lead to increased firing rates and vice versa.

Motor Unit Morphological Information Via Signal Decomposition

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—At the present time, clinicians use concentric needle potentials to aid in determining the average morphological state of a sampling of a muscle's motor units. Such a determination is very useful in the diagnosis of certain diseases and in monitoring their progression. It should be noted, however, that most systems used to perform such analyses are limited to the study of motor units active at low levels of contraction. Therefore, no information is available regarding later recruited motor units, information of utmost importance in some diseases.

This study will create a normative database of concentric needle motor unit action potential peak voltages, areas and number of phases, and the motor unit's corresponding recruitment levels and average firing rates detected during high levels of contraction. Such a database will be generated by using myoelectric signals simultaneously detected by the selective and concentric surfaces of a specialized needle electrode. The selective surface signals will be decomposed into their constituent motor unit action potential trains using the signal decomposition technique. The extracted motor unit action potential trains will then be used to ensemble average the concentric surface signal resulting in estimates of each motor unit action potential shape as detected by the standard clinically used concentric surface. In this way, concentric needle macro potentials can be determined and directly related to their recruitment thresholds and firing behavior, even during high levels of contraction.

The normative database resulting from this study will provide a source of comparison for further studies investigating the clinical significance of combining individual motor unit temporal and morphological information. In particular, this study should also provide previously unavailable information about late recruited motor units.

Common Drive Measurements

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—In this study, our goal is to gain a deeper understanding of the phenomenon of *common drive;* first, by establishing rigorous measures expressing the commonality observed among two signals; and second, by developing a formal model of the muscle force output. The two facets of the study are closely related and should lead to valuable information about the properties of common drive.

A basic tool in assessing the commonality of two signals is the cross-correlation function. A major part of this study will be directed at developing a digital signal processing protocol to make the cross-correlation function a reliable and efficient measure of common drive. The signal processing techniques employed at each step (from the initial firing time information to the final cross-correlation function) will be studied for the purpose of cutting down the computational load and improving the final cross-correlation function. Effort will be directed toward gaining an understanding of the significance of correlation parameters like peak value, peak shift, and period. Ranges will be established for each parameter under varying circumstances.

The proposed mathematical model of muscle force production will consider the individual motor unit twitches and the peripheral feedback involved. Twitch and firing rate characteristics of motor units will be dependent on size and type. By summing the twitch outputs of individual motor units, muscle contractions at various force levels will be simulated using physiologically known recruitment/decruitment schemes and firing rate modulations. The extent to which the homonymous motor unit pool is subjected to common drive will be controlled by the model.

With the model and more complete knowledge of cross-correlation measurements, the effect of varying the amount and nature of common drive to the homonymous motor unit pool will be studied in an attempt to increase our understanding of the effect of common drive on motor unit firing rates and muscle force production. Initial studies show that some of the current signal processing techniques should be modified to reduce the amount of computation without compromising the information content of the final cross-correlation function.

Surface Electrode Design

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—Clear and accurate detection of myoelectric activity from the surface of a muscle is a basic prerequisite for the comprehensive evaluation of muscle behavior. Most of our laboratory and clinical evaluations require some type of surface electrode to observe muscle signal properties such as amplitude, spectral shift, conduction velocity, and location of motor points. These parameters are useful in evaluating the status of an actively contracting muscle.

Over the past few years, we have developed several configurations of active surface electrodes that do not require the use of conductive paste or gels. Each electrode configuration is based around an electronic circuit containing a high-impedance, low-noise, differential preamplifier housed in small, rugged, epoxy packages. We have found that these surface electrodes have the mechanical and electrical stability necessary for reliable and consistent low-noise myoelectric recordings. We now use these "standard" electrodes in a vast majority of our laboratory experiments, such as those concerning muscle fatigue. During the past year, 25 additional electrode units were produced in the Electronics Laboratory.

Based upon the experience gained using our laboratory's "standard" active electrode, we are developing new versions which will expand the electrode's application to studies of dynamic contractions. These contractions occur in activities such as running or exercise and are a more realistic representation of typical muscle function. The rapid flexion and extension of a limb during dynamic contractions impose continually-changing stresses at the skin-electrode interface.

Progress—To address these issues, we are focusing on creating a secure electro-mechanical bond with the skin. Several low-mass, less-obstructive electrode designs that preserve high signal fidelity are being fabricated. In conjunction with this project, we are formulating a series of standard testing procedures to evaluate and compare the electrical and mechanical performance of our surface electrode designs.

Effects of Changing Choline Blood Levels on Muscle Performance

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Sponsor: *National Institutes of Health*

Purpose—This study is part of a larger project regarding the determination of choline's necessity as a nutrient. Work conducted at the Center will focus solely on whether choline blood levels affect human muscle function.

As part of the larger study, subjects will be fed a choline-deficient diet for 3 weeks. At intervals before, during, and after this special diet, subjects will perform muscle function tests. Subjects fed supplemental choline will also be tested.

There are reasons to believe that muscle function will change during choline deficiency. Choline is a quaternary amine necessary for normal mammalian functioning and a precursor for the biosynthesis of phospholipids, essential components of all membranes. In addition, it is necessary for the production of acetylcholine (ACh), the neurotransmitter at work at neuromuscular junctions and responsible for successful muscle activation.

Choline deficiency, if it does indeed cause decreased availability of acetylcholine, could result in intermittent failures of neuromuscular junctions. Normally, neuromuscular junctions have a wide safety margin for successful operation. Thus, it is expected that choline deficiency will cause a prejunctional deficit at the neuromuscular junction, and that these deficits may become evident only after a muscle has been stressed via a fatiguing contraction. Deficient release of ACh at the neuromuscular junction sufficient to cause intermittent failures should cause muscle units to exhibit increased fatigability. Therefore, the study protocol will involve data collection before, during, and after fatiguing contractions. A subject's capability to produce a maximal force will be measured, and the rate of fatigue and recovery will be monitored, using both median frequency and myoelectric efficiency (RMS/Force) measurements. Other projected myoelectric abnormalities due to choline deficiency to be monitored are increased neuromuscular jitter and changes in muscle fiber action potential conduction velocity. Neuromuscular jitter refers to the variability in the time intervals between the arrival of a nerve impulse at a neuromuscular junction and the subsequent firing of the attached muscle fiber. Muscle fiber conduction velocity may change due to structural changes in membrane which may occur as phosphotidylcholine is cannibalized to make free choline available.

In addition to determining the effects of choline blood levels on muscle performance, this study should also reveal significant information about the susceptibility of neuromuscular junctions to free choline blood levels, thereby augmenting our basic understanding of the processes involved in muscle fatigue.

Applications of Neuromuscular Stimulation/Detection System and of Related Software

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Sponsors: *NeuroMuscular Research Center; Politecnico di Torino, 10129 Torino, Italy*

Purpose—In 1985, a joint project was undertaken with the Politecnico di Torino, Italy, to develop optimized strategies for neuromuscular stimulation using a prototype instrument which simultaneously stimulates and records myoelectric responses using surface stimulation and detection techniques. This methodology has a variety of applications in the study of neuromuscular control strategies and in clinical assessment of neuromuscular diseases. The myoelectric signals are elicited voluntarily or by electrical stimulation pulses and are detected using a 4-bar electrode system which allows measurements of spectral parameters and muscle fiber conduction velocity.

An improved version of the system was designed and built at the Department of Electronics of the Politecnico di Torino, Italy. The device features two channels of electromyogram (EMG) detection (each with a single differential and two double differential subchannels), less than 30 μV residual input artifact, and less than 5 μV input noise.

The device has been undergoing extensive evaluation both at the Neuromuscular Research Center and in Torino with satisfactory results. A package of software has been developed for IBM PC/XT/AT or compatible machines and for DEC VAX computers. Such software allows the presentation of the raw signals, of their power spectrum, and of their cross-correlation function. It also computes various parameters (mean and median frequency, conduction velocity, root mean square [RMS], and average rectified value, cross-correlation coefficient, force), and plots them as functions of time or as a function of one with curve fitting of these plots as straight lines or exponential curves.

The new instrument with the related software is the foundation for a series of research projects aimed at investigating stimulated myoelectric activity. Applications are progressing in three major directions: 1) investigation of crosstalk between individual muscles of the lower and upper limb; 2) investigation of crosstalk between muscle compartments; and, 3) investigation of the fatigue behavior of electrically-stimulated muscles (effect of stimulation frequency, effect of full motor unit synchronization, effect of stimulation amplitude and duration on spectral parameters, and on conduction velocity of the elicited potentials).

The technique and acquired experience will be applied to the study of back muscles. The methodology appears suitable and promising for such an application because it avoids the subjectivity implicit in voluntary contractions and allows monitoring of parameters not easily obtainable during voluntary contractions.

Muscle Fiber Conduction Velocity and EMG Spectral Parameters in Voluntary and Stimulated Contractions

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Progress—The relationship between muscle fiber conduction velocity and the spectral parameters of surface myoelectric signals was studied at relatively low and high levels of voluntary and electrically-elicited contractions of the tibialis anterior muscle in 32 experiments performed on 22 healthy subjects. Four-bar electrode, double-differential amplification and cross-correlation techniques were used to measure muscle fiber conduction velocity. Tetanic electrical stimulation, consisting of rectangular pulses of 0.1 ms duration at 20, 25, 30, 35 and 40 Hz, was applied to the most proximal motor point with surface electrodes and with two modalities: high-level stimulation that induced a maximal M wave, and low-level stimulation that produced an M wave near 25 percent of the maximal value. The stimulation and detection system developed at the Politecnico di Torino was used throughout this study.

Results—Measurements obtained from voluntary contractions in all cases showed a positive correlation between voluntary contraction levels and both conduction velocity and spectral parameters, indicating a recruitment pattern in ascending order of conduction velocities. In 44 percent of the stimulated contractions, the mean (and median) frequency and conduction velocity increased with an increasing level of stimulation, indicating a recruitment pattern as in voluntary contractions. In 25 percent of the stimulated contractions, mean (and median) frequency and conduction velocity decreased with an increasing level of stimulation, indicating an order of recruitment reversed with respect to voluntary contractions. In 28 percent of the stimulated contractions, conduction velocity increased, while spectral parameters decreased, and in 3 percent of the stimulated contractions conduction velocity decreased, while spectral parameters increased. Recruitment by electrical stimulation proceeded in ascending order of muscle fiber conduction velocity in 68 percent of the cases and in descending order in 32 percent of the cases.

Implications—These results have led us to conclude that changes in opposite directions of conduction velocity and spectral parameters with increasing stimulus intensity may be due to the effect of tissue filtering properties and may be explained by assuming that an increase in stimulus amplitude sometimes leads to recruitment of faster conducting, but deeper, motor units, and to recruitment of slower conducting, but more superficial, units. The order of motor unit recruitment during surface electrical stimulation may depend upon differing innervation architectures, and is highly affected by individual and/or experimental variations. The order of recruitment during surface electrical stimulation does not necessarily match that observed with implanted nerve electrodes.

These conclusions appear to be particularly important when designing experiments and equipment for the development of functional electrical stimulation techniques.

Surface EMG Crosstalk in the Muscles of the Thigh

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Sponsors: *NeuroMuscular Research Center; Politecnico di Torino*

Purpose—Our interest in measuring electromyogram (EMG) crosstalk in the thigh evolved from a Massachusetts Institute of Technology/Massachusetts General Hospital study in which clear identification of co-contraction between muscles of the thigh and hip was necessary in a patient with an instrumented hip prosthesis. The purpose of the Center's study was to measure crosstalk accurately between antagonistic muscles of the human thigh in order to clarify use of surface EMG to identify co-contraction of muscles during movement.

Progress—A crosstalk measurement relies on the ability to discriminate between a signal originating from the muscle fibers below the detecting electrode and a volume conducted signal from another muscle. Such discrimination may be obtained using electrical stimulation and a double differential recording technique developed at this Center. Myoelectric signals were detected from the skin surface above the rectus femoris, vastus lateralis, vastus medialis, and the lateral and medial hamstring muscles of the thigh. The ratios between peak-to-peak values (PP), average rectified values (ARV), and root mean square values (RMS) of the detected M-waves were used as crosstalk indices. The average values ranged from 2.0 percent to 7.8 percent, with the highest single crosstalk value of 12 percent from the lateral hamstring during stimulation of the vastus lateralis. Neither peak-to-peak values, average rectified values, nor root mean square values appeared to be correlated with leg size.

Results—Our data indicate that a signal detected above a particular muscle of the thigh cannot be assumed to originate exclusively from that muscle. Specifically, up to 12 percent of the signal amplitude detected above the thigh muscles tested may be attributed to an adjacent or contralateral muscle. These results emphasize that caution should be exercised when interpreting surface myoelectric signals when nearby muscles may be active.

This study was undertaken as part of an ongoing collaboration between researchers at this Center and the Department of Electronics of the Politecnico di Torino, Italy. The results were presented at the 9th Annual Conference of IEEE-EMBS in Boston, November 1987.

Skeletal Muscle Reaction to Immobilization

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Sponsor: *Netherlands Organization for Research, Foundation for Biological Sciences*

Purpose—The purpose of this study was the prediction of reaction of human skeletal muscle to immobilization in various conditions regarding length, duration of immobilization period, and position of the limbs.

Progress—A muscle model, relating the architecture of the skeletal muscle to its functional capacity, was formulated and experimentally determined on rat calf muscle and various others.

Application on the human calf muscle using morphological data of human cadavers has been done. The model was also applied in a description of muscular growth. Now it is used in analyzing the effects of various periods of immobilization in different positions, leading to differing muscle lengths. The work is part of a program on "form, function and coordination of skeletal muscles," in which the goal is to relate the experimental analysis of animal muscular function to real life human movements in vertical jumping and running.

Results—The reaction of muscles to immobilization is very complex and not only varies with the muscular position between stretch and shortening, but also varies within the muscle belly, altering architecture, functional capacity, and properties of the contractile tissue, as well as contralateral muscles.

Sarcomeres were counted and electron microscope (EM) preparations were studied in various parts of the muscle to analyze architectural variation due to immobilization.

Future Plans/Implications—During the next year, varying models of immobilization and their effects on muscular fibers (length, number of sarcomeres, type) and their position in the muscle belly will be studied in relation to their functional characteristics (length, force, diagram, etc.). Next, the interaction of these processes and growth (hypertrophy) will be induced and analyzed.

The Frequency Response of Skeletal Muscles: Dependence on Control Strategies and Fiber Types

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Sponsor: *National Science Foundation*

Purpose—The correct frequency response model of a single skeletal muscle has been a long-standing problem. Only unphysiological control inputs (firing rate) could be used or alternate analog models that preassumed the interaction mode of firing rate and recruitment (which were unknown until recently) could be used.

Progress—We tested nine different muscles in the hind limb of the cat under several physiological control strategies with the aid of our newly-developed stimulation system.

It was shown that the frequency response model consists of a second order system with double poles of 1.8 Hz. This was independent of the control strategy used or the force perturbation level. In addition, the poles were muscle-dependent, ranging from 1.7 Hz to 2.6 Hz, according to the muscle-twitch response, pennation, tendon length, and mass. A pure-time delay differentiated the models for fast and slow twitch muscles, being 11 ms and 16 ms, respectively.

Results—It was concluded that FES systems utilizing open or closed loop configuration should carefully consider muscle fiber composition, tendon length, pennation, and mass before designing the optimal system for the muscle under consideration.

B. Muscle Fatigue

Myoelectric Analysis of Human Spine Function: Myoelectric Measurement of Human Muscle Endurance

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Purpose—Inspired by a number of reports which have shown changes in the spectral moment (mean and median power frequency) properties of electromyogram (EMG) signals during sustained isometric contractions, we have, for the past seven years, been investigating such changes in several muscle groups, with special attention to clinical applications. Our major interest has been in the use of technique to obtain information about low back pain patients which would otherwise be unavailable. Our prime objective has been to characterize the changes in spectral moments which can be observed with a single measurand (for example, a time constant or slope measure). We believe that this is essential for clinical applicability of the methodology. Thus, as in strength measurement or blood pressure measurement, norms could be established and an individual's results could be compared to appropriate norms to determine physiologic integrity.

Progress—Information contained in our extensive database collected from large numbers of normal subjects, patients and special subjects such as elite athletes, leads us to the following observations: 1) measurands which would appear to be useful based on previous reports (such as percent change in spectral moment, absolute change, or time constant from curve-fitting with a simple exponential model) show considerable variability in normal populations, when test administration procedures are tightly controlled; and, 2) these measurands, derived in populations where different fatigue characteristics might be expected (orthopedic patients, highly-trained athletes), possess the same degree of variability and exhibit behavior which is not significantly different from established norms.

Results—We conclude that clinically useful discriminating power is now minimal, and that more basic work will be required before clinical utility can be achieved. In the past year we have focused our attention on comparing normal and patient populations using a slow, repetitive exercise (as opposed to a sustained exercise) protocol involving a "reverse situp" trunk lift exercise. The results from these tests (now being prepared for publication) are consistent with our sustained isometric exercise results.

Implications—Clearly, spectral moment changes do reflect important physiologic processes. Our results suggest that more accurate models of these processes are required in order to be able to define measurands which would be clinically-sensitive indicators of muscle endurance. These conclusions temper the initial optimism which is raised upon application of electrodes to a muscle, and observation of spectral moment changes during fatiguing exercise. In fact, we find that the quantitated change in spectral moment characteristics is a more predictable indicator of load level across different subject populations than it is an indicator of endurance. We emphasize that we do not recommend discarding the technique, as the changes in spectral moment are reliable and must reflect important underlying processes. Rather, attention must be focused on relationships of spectral moment changes to other experimental variables, definition of quantitative characterization based on conceptual models, and acquisition of evidence in support of clinical discriminating power based on defined quantitative measures. This suggests that a cautiously optimistic outlook be placed on the use of myoelectric spectral analysis methods in clinical rehabilitation applications.

A Fatigue Protocol for Assessing Pressurized Glove Function

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Sponsor: *Grumman Space Systems*

Purpose—The Muscle Fatigue Laboratory has welcomed the opportunity to demonstrate the suitability of its measurement techniques to new areas of application. In industrial settings, for instance, certain products designed for human use require the measurement of human performance factors. These factors, if measurable, can establish important criteria for improving a product design.

A demonstration of this need is exemplified by a recent collaborative effort between our laboratory and Grumman Space Systems, an operating division of Grumman Corporation. Our assistance was requested to develop a protocol and perform initial measurements to evaluate forearm and hand fatigue associated with the use of a pressurized glove. The glove is part of the pressurized space suit used by NASA astronauts during extra-vehicle ascensions (EVA). One reported difficulty associated with use of the gloves is the premature development of localized muscle fatigue in the forearm and hand. Future designs to improve the glove will be evaluated on the basis of results from a battery of tests under development at Grumman. Our techniques and instrumentation for monitoring localized fatigue from the myoelectric signal appear well-suited for this particular application, since a noninvasive method requiring a relatively simple test procedure was indicated.

We are planning to monitor surface myoelectric signals from two hand muscles and two forearm muscles. The muscle groups selected are active during the opening and closing of the hand. A simple gripping task at a specified duty cycle will be studied to identify different levels of localized muscle fatigue for different glove configurations. Specialized low-profile active electrodes were developed to detect the myoelectric signal from within an instrumented, pressurized "glove box." Myoelectric signals will be processed by the IBM/MFM device described elsewhere in this report. Preliminary measurements were conducted in our laboratory prior to actual, on-site implementation.

Future Plans—Results from this test will be combined with other hand function tests implemented by Grumman to formulate a comprehensive test procedure for future glove designs.

Muscle Fatigue Correlates for Concurrent Myoelectric and NMR Measurements

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Sponsor: *NeuroMuscular Research Center, Boston University*

Purpose—The physiological correlates to the observable shift in the myoelectric frequency spectrum during fatigue are not clearly understood. Although it is widely accepted that this spectral shift is related to a slowing of the myoelectric conduction velocity, the extent to which this phenomenon is related to a change in pH or energy sources within the muscle is not clear. The precise relationship between cellular biochemical events and the electrical manifestations of muscular fatigue has eluded investigators. One of the principal obstacles has been the invasive nature of available laboratory techniques, e.g., tissue biopsy or instrumented probes, to measure intramuscular substrates and metabolites. With recent technical advances in phosphorous nuclear magnetic resonance spectroscopy (NMR), intramuscular pH and other cellular biochemical events can be noninvasively assessed in resting or exercising muscle. NMR spectroscopy units are now available with high-field, super-conducting magnets with a center bore large enough to accommodate intact human limbs and thereby permit bioenergetic measurements of most muscle groups *in situ*.

Progress—At the present time, we are at the initial stages of modifying and testing myoelectric and torque measuring devices to ensure compatibility with the high magnetic fields characteristic of NMR instrumentation. This work is being pursued through the collaborative efforts of the NeuroMuscular Research Center (NMRC) and the Nuclear Magnetic Resonance Laboratory, under the direction of Dr. Martin Kushmerick, at the Brigham and Women's Hospital, Boston, MA.

Preliminary measurements are underway to identify optimal contractile force levels and test durations for establishing a protocol that will accommodate the signal requirements of both methodologies. This procedure will enable us to monitor the change in median frequency as a function of time during, and following, a sustained fatiguing contraction. The median frequency behavior will be compared to concurrent measures of pH and muscular high energy phosphate.

Future Plans—Future goals include the development of studies to establish causality between physiological measures and spectral parameters of the myoelectric signal.

Myoelectric Changes During Fatigue

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—Many studies have shown that during a sustained contraction there is a shift in the myoelectric (ME) signal spectrum toward lower frequencies. The downward shift of the ME signal spectrum has been attributed to a decrease in the velocity of propagation of individual muscle fibre action potentials. Conduction velocity changes, however, cannot account completely for the observed spectral shifts. The goal of this study, which was initiated at the close of 1987, is to monitor other mechanisms that may be important in explaining the observed ME signal spectral changes. These include changes in motor unit firing patterns such as a change in mean firing rate; a change in the variability of the interpulse interval of individual motor units; an increasing degree of synchronization between motor units; and recruitment of new motor units. In addition, changes in the shape of motor unit action potentials, as detected by different detection electrodes, throughout a contraction, will be studied.

Methodology—ME signals will be simultaneously detected during isometric fatiguing contractions using the selective surfaces of a needle electrode, the needle cannula, and a nearby surface electrode. The selective needle signals will be decomposed using the signal decomposition technique. The motor unit action potential trains thus obtained will be used to ensemble average the cannula and surface-detected signals resulting in estimates of some of their constituent motor unit action potentials. Any change in the shape of these cannula and surface macro potentials as a function of force and time will then be analyzed, along with any changes in the firing behavior of the motor units, and compared to changes in the cannula and surface-detected ME signal spectrums.

This project will also continue work done in a previous study at the Center, in which partial decomposition of cannula and surface ME signals was obtained using the macro potentials and their occurrence times. Synthetic signals will then be constructed by changing the firing patterns of individual motor units and/or their motor unit action potential shapes. Each synthetic signal can then be used to simulate cannula and surface signals to analyze further the effect of these changes on a ME signals spectrum.

Muscle Fatigue and the Myoelectric Signal

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—The use of the myoelectric signal to measure objectively the rate at which a muscle fatigues has numerous rewarding prospects. The approach is based on the proven fact that the frequency spectrum of the myoelectric signal detected with surface electrodes changes in a systematic fashion during sustained contractions. High-frequency components decrease in amplitude, while low-frequency components increase. Various studies during the past two decades have searched for the cause of this frequency shift and have attempted to determine whether the change originates from the physical properties of muscle fibers, such as their conduction velocity, or originates from control properties, such as firing statistics. Although the origin of the change is not clearly understood, the effect on the frequency spectrum is consistent and is related to the progression of a sustained muscle contraction. For this reason, it provides a useful mechanism for assessing the involvement of the physiological component in the fatigue characteristics displayed by a task performed by individuals.

The objective measurement of physiological subjective evaluations is essential to offset the seriously erroneous subjective evaluations that occur when psychological components are not isolated. Consequently, it is a vital tool in both industrial and health-care environments, where the evaluation of fatigue-producing tasks is important.

To achieve these goals, we have developed a device called the Muscle Fatigue Monitor (MFM) which automatically, on-line and in real-time, calculates and plots a single-parameter measure of the frequency shift.

Muscle Fatigue Monitor

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Sponsor: *Liberty Mutual Insurance Company*

Purpose—The Muscle Fatigue Monitor (MFM) is an instrument that allows us to objectively measure muscle fatigue in subjects in both laboratory and field environments. The device has evolved through a series of stages, culminating in the present form, which calculates the median frequency of the myoelectric signals that occur during a sustained contraction using electrodes placed on the skin above the subject's muscle. A portable device, the MFM has proven to be a powerful tool for studying the underlying process of muscle fatigue.

In an effort to make the MFM concept available to other researchers, we have developed a more generalized MFM instrument based on the popular IBM-PC computer. Our goal was to create an integrated fatigue measurement system for both research and clinical environments. Such a system would allow researchers to investigate the fatigue process of more complex muscular activity.

Progress—The heart of the new MFM system is the dual-channel median frequency processing card developed by our laboratory in 1986. When these cards are installed in an IBM-PC series computer and coupled with appropriate software, they form a powerful and flexible data acquisition system. Unlike other signal processing techniques, this instrument can process up to 10 channels of fatigue-related information in real-time, and immediately present results to the experimenter. This feature should prove useful for future clinical investigations.

The present focus of the MFM system development is in the area of software. The first version of a modular software package has recently been completed which allows the operator to configure the MFM system for a variety of applications, such as fatigue analysis of lower back muscles.

Future Plans—To date, many researchers have expressed an interest in obtaining the new IBM-PC based MFM system. As a result, plans are underway to produce a limited number of MFM systems and evaluate the feasibility for large scale production of the device, so that it can be made available to both the research and clinical communities.

C. Ligaments and Tendons

Structural and Functional Properties of Normal and Healing Ligaments

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A188-3RA)*

Purpose—We have studied the effects of partial and total loss of anterior cruciate ligament (ACL) function on the healing of the medial collateral ligament (MCL) in the canine, with respect to varus-valgus (V-V) knee laxity, as well as structural and mechanical properties of the femur-MCL-tibia (FMT) complex. The healing of the MCL, and the factors that may influence its healing, have been the focus of much investigation. In particular, an intact ACL is felt to provide stability to the knee that may account for the favorable results of MCL healing observed following conservative, non-operative treatment of MCL injury.

Methodology—In one group (intact ACL), the left MCL was surgically exposed and completely transected without repair. In the second group (partial cut ACL), the anteromedial portion of the left ACL was sectioned, in addition to the MCL, while in the third group (complete cut ACL), both the left ACL and MCL were transected.

Results—The results suggest that healing of the non-repaired MCL injury is affected by the degree of ACL function. Both V-V knee laxity and mechanical properties of the healing MCL recovered more slowly in specimens with associated ACL injury. The formation of a large MCL healing mass may explain the relatively rapid recovery of the normal structural properties of the femur-medial collateral ligament-tibia (FMT) complex. Time is required for this healing mass to be replaced by tissue more characteristic of the normal MCL.

In addition, the effects of strain rate on the structural properties of the FMT complex, and on the mechanical properties of the MCL, were studied using New Zealand white rabbits from two age groups: skeletally immature (3-and-a-half-months old with open epiphyses) and skeletally mature (8-and-a-half-months old with closed epiphyses). The structural properties of the FMT complex (load-deformation curves) were found to be strain-rate sensitive for both groups, and values of tensile strength, load, deformation, energy absorbed, and strain at failure increased significantly for both the skeletally mature and skeletally immature complexes. With skeletal maturity there were also substantial increases in the size of the MCL. However, the stiffness of the ligament substance (slope of the stress-strain curves) was minimally strain-rate sensitive for both groups. All samples from the immature animals failed by tibial avulsion, and all samples from the mature animals failed within the ligament substance. Histological sections of the ligament substance and insertion sites from the pre-failed and failed samples were made, and these observations were correlated with the biomechanical findings. For the rabbit model used in this study, we conclude that skeletal maturity has more influence on the biomechanical properties of the MCL than strain rate.

Publications Resulting from This Research

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Effect of Ligamentous Instability on Knee Joint Proprioception

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A370-RA)*

Purpose—The purpose of this study is to test the hypothesis that anterior cruciate ligament-injured knees have impaired proprioception perception that may contribute to accelerated deterioration of these knees. Proprioception is tested in two ways in this study. The first is to test the ability of a patient to reproduce a given position of the lower leg in space. The second is to test the patient's ability to perceive motion at the knee-controlling position, velocity, and acceleration at very low velocities.

Progress—A study of 11 anterior cruciate-deficient subjects and 10 control subjects using the second test (kinesthesia) has been completed. This study demonstrated a significant deterioration in the ability of the anterior cruciate-deficient limb to detect the onset of slow passive motion. This study was performed using previously-designed equipment.

More sophisticated measuring equipment has been completed, and a second study is in the planning stages for recruitment of subjects to use this equipment. This study is aimed at subjects who have had anterior cruciate reconstruction, whereas the previously-mentioned study consisted of a group of subjects who had not undergone surgical reconstruction.

Future Plans/Implications—As more information about proprioceptive ability is generated, and how it is affected by surgical intervention after injury, the possibility that this technique may be suitable as a clinical test of proprioception will be evaluated. This may assist the treating physician in making surgical and rehabilitation decisions with these patients.

Publications Resulting from This Research

Proprioception in the Anterior Cruciate Deficient Knee. Skinner HB, Cannon WD, Barrack RL, *Am J Sports Med* (accepted for publication).

Award for Excellence in Research as Applied to Sports Medicine. *American Orthopedic Society for Sports Medicine*

Treatment of Variable Partial Flexor Tendon Lacerations

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Purpose—Penetrating trauma to the hand frequently produces partial lacerations of the digital flexor tendons. While primary surgical repair of complete flexor tendon lacerations has been generally accepted, the role for tenorrhaphy in the management of incomplete tendon injuries remains controversial. Described complications following treatment of these injuries include: tendon triggering, entrapment of tendon flaps, late rupture, and adhesion formation. Additional surgery with extended periods of occupational therapy and rehabilitation are often necessary in these cases. A better understanding of the effects of different treatment protocols would lead to improved management of partial tendon lacerations, while minimizing the required rehabilitation period.

The key questions in defining optimal management of partial flexor tendon lacerations include: 1) What post-operative load can partially-lacerated human tendons withstand? 2) What is the role for tenorrhaphy in the treatment of these injuries? and, 3) Is there a place for more delicate but less traumatic suturing techniques in preventing the complications of loose tendon flaps while minimizing the post-operative tendon scarring?

Our hypothesis is that the strength remaining in a partially-lacerated tendon is *directly proportional* to the absolute cross-sectional *area of tendon left intact,* and only *indirectly related* to the relative *percentage of tendon area lacerated*. If this hypothesis proves correct, measurement of the amount of tendon left intact would allow an estimate of the strength remaining in a partially-lacerated tendon.

Progress—In preliminary investigations, we have developed an instrument we call the "tenotome." This device allows us to produce very consistent partial tendon lacerations by providing absolute control over the amount of tendon left intact.

Future Plans—Using this instrument, we plan to investigate the tensile strength of lacerated human cadaver and chicken tendons. We also plan to study the effect of various treatment regimens on the healing abilities of experimental lacerations.

The specific short term goals of this project are: 1) using the tenotome to vary the amount of tendon left intact, develop a strength curve for partial tendon injuries in experimental and fresh cadaver flexor tendons; 2) compare the healing abilities of chicken lacerations treated conservatively and surgically using histologic examination and evaluation of tendon tensile strength and gliding function; and, 3) use the tenotome to develop a consistent experimental model for oblique tendon flaps.

Meeting these objectives will require a year of full-time investigation. Our long-term goal would be to apply the results of our experimental studies to the clinical treatment of partial flexor tendon injuries.

Laser Biostimulation of Healing Tendons: A Pilot Study

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Purpose—The purpose of this study is to determine whether laser biostimulation quickens the healing process of tendons. We shall tenotomize, suture, and immobilize the rabbit Achilles tendon unilaterally. In this experiment, the effects of 5 doses ranging from $1mJ/cm^2$ to $5mJ/cm^2$ will be determined in 5 groups of rabbits. On post-operative day 21, laser-treated and control tendons will be excised for testing. The breaking strength of the excised tendons will be determined by pulling each tendon to rupture, on an Instron machine. Tendons for electron microscopy will be prepared by standard histological techniques, trimmed, sectioned, and then viewed under the electron microscope. Morphometric measurements of the sizes, densities, and distribution of the collagen fibrils produced will be made with a computerized digitizer tablet.

Ligament Insertions: Relations in the Moving Knee

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A363-RA)*

Purpose—The purpose of our research is to quantitatively describe all possible isometric repair techniques. To accomplish this, we measure the 3-dimensional anatomy and 6 degree-of-freedom motion of cadaver knees. Computer search techniques are then used to find all isometric repair sites. We use computer-generated 3-dimensional "isometry maps" to present our findings in a manner useful to surgeons.

Results—We have published comprehensive descriptions of isometric repair techniques for the anterior and posterior cruciate ligaments, and for lateral extraarticular tenodesis of the iliotibial band. These are the most complete descriptions in the literature, and are widely-used by practicing orthopaedic surgeons as guides to graft placement. Similar descriptions for the collateral ligaments are in preparation.

Other issues besides isometry are important in ligament reconstruction. Our recent research has demonstrated that even if the central fibers are nearly isometric, the peripheral fibers are not, and also that large bending angles necessarily occur at the bone tunnel fixation sites.

This raises the issue: What mechanical effects are associated with noncollinear fiber geometry? In two published abstracts and in a lengthy manuscript submitted for publication, we have developed a comprehensive theory of the mechanics of bending and twisting fibers in ligaments and tendons. The theory makes very detailed predictions about the distribution of internal stresses in ligaments and tendons, contains no adjustable parameters, and requires as input only information readily contained from micrographs. It is the first general theory ever developed of the equilibrium mechanics of ligament and tendon fibers.

The theory predicts that large transverse pressures between fibers are necessarily generated at the insertion sites of anatomic ligaments and tendons. These pressures are somewhat mitigated, but not eliminated, by the "splayed" fiber geometry typical of anatomic attachments. We hypothesize that the avascular nature of ligament attachments is a consequence of these pressures, as is the presence of the so-called "fibrocartilagenous" layer.

The theory predicts that normal structure/function relations are severely deranged at bone tunnel fixation sites of grafts. Internal pressures in excess of 10,000 mm/Hg are predicted to be generated by standard clinical drawer tests of graft laxity (i.e., a 20-pound tension on the graft). We have experimentally demonstrated that these large pressures do in fact occur. These experimental results are being prepared for publication.

Implications—The magnitude of the internal pressures is extremely sensitive to surgical technique. One important variable is the radius of rounding of the tunnel edge: the greater the radius, the less the pressure. Also important is the orientation of the tunnel: the less the bending, the less the pressure. Thus, isometry is only one of many factors to consider when planning a ligament reconstruction.

Publications Resulting from This Research

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XII. Neurological/Vascular Disorders

A. General

Towards Better Methods of Nerve Repair and Evaluation

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B003-4RA)*

Purpose—Our purpose is to develop a novel microelectronic neural interface to improve functional recovery in cases of peripheral nerve injury.

Methodology—If individual axons in a regenerating peripheral nerve (or fascicle thereof) can be accessed via a bidirectional neural interface, afferent and efferent signals can be re-directed after a nerve injury to improve clinical recovery. As well, such interfaces can be utilized for direct control of motor prostheses. A silicon-based integrated circuit (i.c.) containing interface electronics and microelectrodes in a square, planar array will be placed between the two ends of a severed peripheral nerve. The i.c. will be held in place utilizing a surgical nerve coupler.

Progress—We have undertaken a project leading toward the development of direct man-machine interface. The project is progressing through the following stages: 1) *connection*—re-apposing the severed peripheral nerve sections; 2) *communication*—establishing an electronic interface to the nerve at the level of individual axons; and, 3) *control*—managing the flow of efferent and afferent information in the nerve to attain the desired clinical result.

Initial work on the communication aspect of the project involved the use of laser-drilled via holes in blank silicon substrates. This work permitted the determination of optimal ranges of hole sizes to capture *individual* regenerating axons. Laser-drilling of holes renders the surface of the silicon wafer unsuitable for the ultimate fabrication of the microelectronic devices required to obtain functional neural interfaces (due to crystalline defects and surface ablation). Thus, a more appropriate via hole fabrication technology was sought. Since the Palo Alto VAMC does not have semiconductor fabrication capabilities, Stanford's facilities were used.

A plasma etching process, which involves the bombardment of exposed areas of the silicon wafer with perpendicularly-oriented halogen free radicals, was developed over the past year at the Stanford Center for Integrated Systems. We have successfully fabricated via holes through silicon substrates using this technique.

The next fabrication step under development is the passivation or protection layer which will protect the on-chip microelectronics from the effects of alkali ions in body fluids, which can permanently render such devices useless. The process chosen is a Plasma-Enhanced Chemical Vapor Deposition technique which we use to deposit silicon nitride on top of the on-chip structures. It is inherently highly conformal and we have demonstrated its capability to coat the insides of the via holes, preventing lateral migration of the alkali ions.

Techniques for deposition of the microelectrode metal, iridium, have been demonstrated at the Stanford University Ginzton Applied Physics Laboratories. An electron-beam evaporation technique is used.

Thinning of the wafers to a thickness through which the axons can regenerate is a process currently under development. We have chosen to utilize a mechanical lapping process, and are currently characterizing this process. Wafers are mechanically lapped to within tens of microns of their target thickness and then chemically thinned by hand to final dimensions to preserve delicate structures.

Devices containing all critical structures other than active microelectronic devices are being fabricated in order to integrate all aspects of these fabrication techniques. We refer to these devices as *passive* neural interfaces as opposed to the ultimate *active* versions which will contain on-chip transistor circuitry.

Implications—These passive chips will match the properties of the final versions of the devices as closely as possible and should permit the first recording and stimulation studies ever carried out with such arrays in the middle of 1989. Information obtained from these studies will be integrated into the design of the active arrays.

Publications Resulting from This Research

Development of Chronic Implant Neural Prosthesis Microelectrode Arrays. Kovacs GTA, Stephanides MC, et al., *Proceedings of IEEE MONTECH '87 Conference on Biomedical Technologies*, Montreal, 1987.

Design of Two-Dimensional Neural Prosthesis Microelectrode Arrays. Kovacs GTA, Stephanides MC, et al., *Proceedings of the Ninth Annual Conference, IEEE Engineering in Medicine and Biology Society*, Boston, 1987.

The Development of a Microelectronic Axon Processor Silicon Chip Neuroprosthesis. Rosen JM, Kovacs GTA, Stephanides MC, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:675-677, 1987.

Design and Implementation of Two-Dimensional Neural Interfaces. Kovacs GTA, Storment CW, et al., *Proceedings of the Tenth Annual Conference, IEEE Engineering in Medicine and Biology Society*, New Orleans, 1988 (in press).

Stanford University General Purpose Microelectrode Fabrication Process. Kovacs GTA, Storment CW, et al., *Proceedings of the Tenth Annual Conference, IEEE Engineering in Medicine and Biology Society*, New Orleans, 1988 (in press).

Effect of Collagen Type III on Axonal Regeneration in Artificial Nerve Graft

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B387-RA)*

Purpose—In some traumatic peripheral nerve injuries, significant loss of nerve tissue may result in a gap too wide for an end-to-end anastomosis; therefore, a nerve graft is necessary to bridge the gap. Currently, the nerve autograft is the preferred graft. However, its major disadvantage is the limitation of the donor nerve. Consequently, an artificial nerve graft (ANG) which consists of a passive conduit and a growth medium is desirable.

The development of an ideal ANG is highly desirable because it not only solves the problem of availability, but also provides better axonal regeneration for better functional recovery.

Various types of biological tubes—arteries, veins, pseudosynovial tubes have been used with some success. A synthetic biodegradable tube is better because it will be resorbed, leaving only the regenerated nerve, and also because it can be made available at any time, size, and quantity.

Previous work done using such a biodegradable tube made of polyglycolic acid (PGA) and filled with a hypoantigenic collagen gel, has shown that axons are able to regenerate into the collagen medium; but the rate of regeneration is less when compared with that in the autograft. Therefore, we are interested in determining the facts which will enhance the rate of nerve regeneration.

The role of collagen in wound repair as well as its "non-structural" functions are well established. However, the role of collagen in nervous tissue repair is still unclear. Biochemical analysis of various mammalian (rat, rabbit, and monkey) peripheral nerves done in our laboratory has confirmed previous histochemical studies suggesting the selective presence of collagen type I and type III in the epineurium and the endoneurium respectively. Other studies have shown that collagen type III is present in higher quantity in early wound repair, as well as having higher affinity to certain substrates.

This study is to determine whether the addition of collagen type III to the ANG growth medium can greatly enhance axonal regeneration.

Methodology—This is the first of two parts of the study. This first part is to determine the ideal mixture of collagen type I and type III. In each animal, a 0.5 cm long segment of nerve will be removed from the distal transected end of both peroneal nerves. One randomized side in each animal will be repaired with an autograft, using the segment removed from the opposite nerve using 10-0 nylon suture. The other side will be repaired using an artificial nerve graft. The artificial nerve graft will be composed of a PGA tube (available from Davis and Geck Co., Pearl River, NY) filled with a mixture of varying ratios of collagen type I and type III. The different mixture ratios chosen are: 100 percent type I, 75 percent type I and 25 percent type III, 50 percent type I and 50 percent type III, 25 percent type I and 75 percent type III, 100 percent type III.

Progress—Nerve repair was done on a total of 15 animals (3 with each of the above mixture ratios). Nerve biopsies and electrophysiology were done in 10 animals at 6 to 7 months post-operatively.

Preliminary Results—Preliminary results appear to indicate that collagen type III has some axonotrophic effect on axonal regeneration in an artificial nerve graft in a rat. Electrophysiology on the remaining animals and histologic correlation are crucial data needed prior to starting the second part of the study.

Publications Resulting from This Research

Artificial Nerve Graft Compared to Autograft in a Rat Model. Rosen JM, Pham HN, Abraham G, Harold L, Hentz VR, *J Rehabil Res Dev* 26(1): 1-14, 1989.

Comparison of Treatment Programs for Multiple Sclerosis Rehabilitation

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B395-SCI)*

Purpose—The goal of this project is to examine the effectiveness of interdisciplinary team care, coordinated by a nurse practitioner, in comparison with standard neurological care. The primary hypothesis is that team care that provides a comprehensive assessment of the patient's condition, addresses both physical and psychosocial needs, and sets realistic goals for rehabilitation, will improve quality of life, maximize functional status, and obviate preventable complications of multiple sclerosis at a cost comparable to traditional care.

Progress—We are comparing multiple sclerosis patients at the Denver and Portland VAMC's using standardized measures of patient satisfaction, quality of life, happiness, functional limitation, neurologic impairment, caregiver burden, utilization of VA and non-VA services and medical condition. The patients in Portland will continue to receive comprehensive neurological care. In Denver, the patients will enter the interdisciplinary team clinic, which is staffed by a nurse practitioner, two neurologists, a physiatrist, an occupational therapist, a physical therapist, a psychologist, a social worker, and visiting nurses. The team conducts a comprehensive assessment and institutes diagnostic and therapeutic measures appropriate to the patient's condition and needs. The nurse practitioner is the coordinator of the patient's care and acts as a primary care provider and case manager for the patient. All patients will be reevaluated at 6 and 12 months for change in the various outcome measures. Thus far, approximately 25 patients have been entered into the study at each site and have completed the initial study measures.

Future Plans—The goal is to study at least 100 patients at each site. Preliminary results of the baseline evaluations will be available within the next 6 to 8 months.

Assessing the Need for Management of the Neurogenic Bowel in the Pediatric Population

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Sponsor: *Research Department, Hugh MacMillan Medical Centre*

Purpose—The objective of this study is to develop a database identifying present management practices and factors that might influence bowel management in a sample of spina bifida children.

Progress—The study involved 65 children ranging in age from 0 to 16 years who attend the bimonthly combined Spina Bifida Clinics and the monthly Teen Bifida Clinic. The subjects were chosen randomly from the total sample and then grouped by age and sex. A computer-compatible questionnaire, consisting of 54 questions, was developed and individually administered by an experienced registered nurse/research assistant, through prescheduled parent/child/teen interviews.

Individual interviews were planned in order to gain a thorough understanding of: 1) early and present bowel functioning; 2) methods of bowel management; 3) parental knowledge of factors affecting bowel routine on child and family; and, 4) parents' assessments of need for a bowel management program; and, 5) urinary functioning and management.

The data has been tabulated on a question-by-question basis for all subjects grouped by age and sex. Present activities involve preparing a final report for publication.

Maximal Exercise Performance of Individuals with Multiple Sclerosis: Influence of Disease-Related Muscular- and Temperature-Induced Dysfunction

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Sponsor: *Levine-Rubenstein MS Research Fund*

Purpose—The primary goal of this research is to evaluate the aerobic exercise capacity of individuals with multiple sclerosis (MS), and to determine factors that limit exercise capabilities in this patient population. Specific objectives include: 1) development of a recumbent cycle ergometer capable of operation in an air and water environment; 2) assessment of several fitness characteristics, such as pulmonary function, body composition, and leg muscle strength, that might influence exercise capability; 3) evaluation of maximal aerobic exercise capacity; and, 4) comparison of the physiologic responses of this population with matched controls during prolonged recumbent cycling in the two environments.

Progress—A recumbent cycle ergometer (RBERG) was developed and validated in both an air and water environment and compared to a standard upright cycle ergometer (BERG) in air. An existing computer program for analysis of metabolic data was modified to monitor and record pedal frequency and rectal temperature. Currently, 11 MS and 9 able-bodied (AB) subjects are participating in the project. The MS subjects were referred by local neurologists from previously-diagnosed cases and screened via a standard neurological examination and a visual evoked potential prior to acceptance into the study. Subjects in both groups have been assessed for abnormalities in cardiovascular reflexes using an automated data collection and analysis computer program developed for this project. Evaluation of pulmonary function, body composition, and isokinetic leg strength (Kin-Com isokinetic dynamometer) has been completed on 19 subjects.

Preliminary Results—We have compared the newly-developed RBERG to the BERG and found no significant difference in metabolic or cardiopulmonary responses at given submaximal power output (PO) levels. Further analysis of the effects of water upon the operation of the RBERG have indicated that a greater metabolic cost is required (0.08 l/min^{-1}) to perform at the same indicated exercise PO in water. More recently, 4 MS and 4 AB subjects have been compared on the RBERG during submaximal and maximal exercise. Oxygen uptake ($\dot{V}O_2$) was significantly lower for the MS subjects at all submaximal stages, as well as at maximal exercise (2.33 versus 3.29 l/min^{-1}). Heart rate was also significantly lower during submaximal exercise for the MS group. This may indicate that the MS group has deficient O_2 delivery to exercising muscles, which may be due in part to inadequate response of cardiovascular reflexes of both a central and peripheral nature.

Future Plans/Implications—Having completed the initial set of tests, the present groups will undergo evaluation of metabolic, cardiorespiratory, and thermoregulatory responses during submaximal and maximal exercise in both environments using the RBERG. From these results, we hope to gain an understanding of the manner in which MS affects normal physiologic responses in the exercise setting. If exercise capacity can be improved in water due to enhanced heat dissipation, the potential for achieving a higher level of physical fitness would be greater through training in this environment.

Publications Resulting from This Research

Metabolic Responses During Cycling in Water Versus Air. Ponichtera JA, Davis GM, Glaser RM, Servedio FJ, Collins SR, *Med Sci Sports Ex* 19(2), Suppl.S83, 1987.

Physiologic Responses of Men with Multiple Sclerosis During Aerobic Exercise. Ponichtera JA, Glaser RM, Davis GM, Servedio FJ, Collins SR, *Med Sci Sports Ex* 20(2), Suppl.S35, 1988.

A Recumbent Cycle Ergometer for Disabled Individuals. Ponichtera JA, Glaser RM, *Proceedings of the ICAART Conference*, Montreal, 158-159, 1988.

Comparison of Concentric and Eccentric Isokinetic Strength Between Multiple Sclerosis and Healthy Able-Bodied Individuals. Ponichtera JA, Rodgers MM, Glaser RM, *Med Sci Sports Ex* (in press).

Automated Autonomic Nervous System Function Analysis System. Ezenwa BN, Figoni SF, Glaser RM, Ponichtera JA, Rodgers MM, Almeyda JW, *Proceedings of the 10th Annual Conference of IEEE/EMBS* (in press).

Rehabilitation Research and Training Center in Progressive Neuromuscular Diseases, UC Davis

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Sponsor: *National Institute on Disability and Rehabilitation Research; U.S. Department of Education*

Purpose—This program includes two research sections (clinical and preclinical), and one training and dissemination of information section. The clinical section deals with comprehensive rehabilitation research in children and adults with neuromuscular diseases (NMDs). Its general goals are to: 1) evaluate and develop quantitative measures of neuromuscular function leading to improved techniques for assessing physical functioning; 2) evaluate the effects of various therapeutic interventions on the natural course of disease processes and functional ability; 3) develop effective rehabilitation interventions to improve vocational, education, and independent living options; and, 4) rapidly disseminate findings, with special emphasis on applicability to treatment of NMDs.

The preclinical research section has a single goal: to expedite development of therapeutic measures to aid in rehabilitation of individuals disabled by progressive NMDs. All five preclinical projects utilize disease "models" and rely heavily on multidisciplinary methodologies (ranging from functional tests to muscle grafts and molecular biology). To expedite application in a clinical setting, a comprehensive intervention development program has been designed. It includes both heredity and induced-disease models, a focus on development and use of quantitative evaluation methodologies, and evaluation of both physical and pharmacological interventions.

The primary goal of the training and dissemination section is to enhance utilization of successful research outcomes by: 1) training appropriate target populations in the use of improved methodologies and treatments in service delivery settings; and, 2) rapid dissemination of information to all appropriate target groups to expedite utilization of research outcomes and stimulate additional research. Specific objectives are designed to: 1) provide advanced training in rehabilitation research for a comprehensive target population; 2) train rehabilitation service personnel and other appropriate individuals to improve practitioner skills based on new research-derived knowledge; 3) provide training packages that make research results available to service providers, researchers, educators, disabled individuals, parents, and others; 4) provide technical assistance or consultation responsive to concerns of service providers and consumers; 5) disseminate research findings through presentations at national/international meetings, publication in professional and consumer-oriented journals and books, and through audiovisual and telecommunications media; and, 6) provide a national resource and referral center for rehabilitation research in NMDs.

Publications Resulting from This Research

The Effect of Therapeutic Exercise on Modifying Strength in Myotonic Muscular Dystrophy. Aitkens S, McCrory M, Bernauer EM, Fowler Jr WM, *Arch Phys Med Rehabil* 69:782, 1988.

Glucocorticoids in Muscular Dystrophy: Beneficial Effects of Dexamethasone on Avian Myopathy. Entrikin RK, Abresch RT, Bradford DP, Larson DB, Longley KJ, Wilson BW, *FASEB J* 2:2722-2725, 1988.

Drug Evaluation for Human Neuromuscular Diseases: Avian Muscular Dystrophy. Entrikin RK, Abresch RT, Bradford DP, Lantz RH, *Arch Phys Med Rehabil* 69:790, 1988.

Muscular Dystrophy: Isoproterenol-Dexamethasone Syngerism in Chickens. Entrikin RK, Abresch RT, Lantz RH, Larson DB, Bradford DP, *Soc Neurosci Abs* 14 (Part 1):676, 1988.

Neuromuscular Diseases. Fowler WM Jr, in *Rehabilitation Medicine,* J. Goodgold (Ed.) (Chap. 22), 298-316. St. Louis: C.V. Mosby Co., 1988.

Epidemiology of Scoliosis in Duchenne's Muscular Dystrophy. Lord J, Varzos N, Behrman B, Lieberman JS, Fowler WM Jr, *Arch Phys Med Rehabil* 69:742, 1988.

Dominant and Non-Dominant Strength in Normal Individuals and Neuromuscular Disease Patients. McCrory M, Aitkens S, Fowler W, Bernauer E, McCrory M, Aitkens S, Fowler W, Bernauer E, *Phys Ther* 68:862, 1988.

Comparison of Pulmonary Function Between Myotonic Muscular Dystrophy (MMD) and Duchenne Muscular Dystrophy (DMD). Yang C, Abresch R, Fowler W, Lieberman J, *Arch Phys Med Rehabil* 69:771, 1988.

Myotonic Mice: Effects of Tubocurarine on Muscle Contractility. Entrikin RK, Abresch RT, *Muscle Nerve* (in press).

Management of Musculoskeletal Complications: Weakness and the Role of Exercise. Fowler WM, Jr, *Physical Medicine and Rehabilitation: State of the Art Reviews/Advances in the Rehabilitation of Neuromuscular Diseases,* Philadelphia: Hanley & Belfus, Inc. (in press).

Mortality from Neurologic Disorders: National and International Comparisons

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Sponsor: *National Institutes of Health*

Purpose—Because death certificate data are limited by possible misdiagnosis, incomplete case ascertainment, errors in coding, etc., detailed mortality information on some neurologic diseases for the entire United States is not available. Analysis of mortality data can be particularly useful for some neurologic diseases because these may contribute to death indirectly. Since there are no uniform criteria for what constitutes the underlying cause of death in patients, it is important to examine all deaths in which a disease is listed as an underlying, immediate, associated, or contributory cause of death to get more complete information about the relationship between the disease and death.

Results—Association of diseases occurring at the time of death was also studied for all deaths occurring in the United States for many neurologic diseases. Diseases occurring together may provide important information in the search for etiology of diseases. Such detailed analysis of mortality data has been done for Alzheimer's disease and related diagnosis, motor neuron disease, Down's syndrome, spina bifida, hereditary ataxias, Huntington's disease, epilepsy, strokes in patients without hypertension, multiple sclerosis, and Parkinson's disease, for 1971, and 1973 to 1978. The overall patterns which have emerged have been useful in evaluating trends over time and in formulating etiologic hypotheses.

Survey of Major Neurological Disorders in Copiah County, Mississippi

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Sponsor: *National Institutes of Health*

Purpose—To determine the prevalence of frequently-occurring neurologic disorders in a biracial population, a survey of households and chronic care institutions was carried out for all residents of Copiah County, MS. Along with a complete census, interviews were held using extensive questions about diagnoses, signs, and symptoms of neurologic disorders. Over 97 percent of eligible households participated, comprising 23,842 persons (49 percent black, 50 percent white, 1 percent other).

Results—Persons with responses suggesting one or more of these disorders were examined by a neurologist who used defined diagnostic criteria. Age-adjusted prevalence ratios for cerebral palsy, epilepsy, stroke, and severe dementia were somewhat higher in blacks than in whites, while the age-adjusted prevalence ratio for essential tremor was slightly higher in whites. For Parkinson's disease, there was no difference in age-adjusted prevalence ratios between the races. With respect to particular disabilities in persons with the disorders mentioned above, it was found that proportionately more institutionalized men than institutionalized women were functionally disabled.

B. Arthritis

Biochemical Analysis of Synovial Activation in Joint Dysfunction

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A052-5RA)*

Purpose—Our previous VA funding has supported a project with the twin aims of examining wear particles biochemically, as possible mediators of arthritic degeneration within joints, and ferrographically, as diagnostic and prognostic indicators of joint health and disease. Both aims have been successful. We have clearly identified wear particles within human joints as agents of articular deterioration. In particular, our accumulated evidence strongly suggests that synovial activation in response to these particles is the key process through which they act. The ferrographic studies have permitted, in principle, the "condition monitoring" of human joints. With progress on all fronts, the project has evolved, diversified, and thus become too unwieldy to be continued as a single entity. For this reason, we propose to separate the ferrographic from the biochemical aspects of the work, submitting each as a separate proposal.

This proposal concerns the continuation of the biochemical analysis. It has two aspects. The first is to determine the biochemical mechanisms through which wear particles activate synovial cells. The second is to examine in greater detail our hypothesis that certain metals used in the construction of prosthetic joints activate cells of the synovial type, and that this promotes aseptic loosening of the implant.

With regard to the first aspect, we shall concentrate on the manner in which wear particles promote the synovial production of collagenase. We are concentrating on this enzyme, partly because it controls what is probably the rate-limiting step in the irreversible degradation of cartilage, and partly because we have a cDNA probe for the mRNA of this enzyme. In addition to measuring the abundance of the collagenase mRNA, we will evaluate the role of changes in cellular concentrations of Ca^{2+}, cAMP and cGMP, and alterations in the pattern of protein phosphorylation. Recently, we have shown that wear particles also provoke the synovial release of interleukin-1 (IL-1). As synovial cells are also activated by IL-1, there is the potential for an important positive feedback loop, which we shall examine.

The second aspect of this proposal concerns synovial activation by implant metals. A variety of metals will be tested, both as particles and as soluble salt solutions, upon synovial cell cultures. Key findings will be confirmed under *in vivo* conditions by injecting the materials into rabbits' knee joints. The mechanism of synovial collagenase release in response to metals will be examined in the manner indicated above for cartilaginous particles.

C. Low Back Pain

Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

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Sponsors: *VA Rehabilitation Research and Development Service (Project #367-RA); Department of Clinical Investigation of the US Army Medical Department*

Purpose—To evaluate the effectiveness of psychophysiological ways to assess chronic low back pain.

Methodology—Subjects with low back pain are given a complete physical examination and other objective medical tests. They are then interviewed by a psychologist and given both a standard and a specially modified Minnesota Multiple Personality Inventory (MMPI). They then participate in 4 weekly muscle tension and heat pattern recordings while experiencing various intensities of low back pain.

Results—This study has run about half of its subjects. Initial results indicate that subjects with low back pain do not change many of their MMPI responses depending on whether or not they are in pain when answering the questions. To date, we have not found clear relationships between low back or leg thermograms and either intensity or diagnosis of low back pain. Paraspinal muscle tension correlates well with pain intensity, but results differ somewhat, depending on the diagnosis. However, people producing asymmetrical thermograms (different at greater than 1 degree C), tend to produce normal surface electromyograms (EMGs) and vice-versa.

Future Plans—We will continue the study until sufficient subjects are completed to permit us to draw clear conclusions from the data.

Publications Resulting from This Research

Thermographic Correlates of Chronic Pain: Analysis of 125 Sequential Subjects Incorporating Evaluations by a Blind Panel. Sherman R, Barja R, Bruno G, *Arch Phys Med Rehabil* 68:273-279, 1987.

Electromyographic Recordings of Five Types of Low Back Pain Subjects and Non-Pain Controls in Different Positions. Arena J, Sherman R, Bruno G, Young T, *Pain* (accepted for publication).

Muscle Fatigue and Back Pain

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A391-RA)*

Purpose—As many as 75 million Americans now suffer from severe lower-back pain and each year 7 million more people develop this problem. Despite the many millions of dollars spent on innumerable treatments for the back, the majority of patients have chronic, remitting symptoms. Improved methods for assessing back disorders could help to diminish the problem and the financial burden of this disabling condition.

Progress—We have developed and are implementing a technique to provide the clinician with an objective index with which to measure treatment outcome for lower-back musculature. This technique estimates the fatigue rate of contracting muscles by measuring the shift occurring in the frequency spectrum of the surface-detected myoelectric signal. The dynamic interaction of synergistic back muscles during fatiguing contractions can be represented by "fatigue patterns" created by the frequency shifts occurring in different muscles. Differences in these patterns associated with lower-back disorders may represent functional disturbances in back muscles.

To implement this technique, a restraining device was designed and constructed to stabilize the trunk in selective positions from sitting to standing. The device is equipped with strain-gauge load cells to monitor flexion, extension, or rotation torques of the trunk. A similar, portable device was recently completed for testing patients. This device is part of a computer-aided system that will analyze multiple channels of myoelectric signals to compute the median frequency of the signal on-line and in real time for each channel. In addition, preliminary modifications of another device will permit the analysis of multiple channels of myoelectric signals and will track the median frequency of the signal.

Data from numerous chronic lower-back pain patients and normal controls are being collected and analyzed for several areas of investigation. First, we are continuing to document the repeatability of the myoelectric signal parameters that comprise a fatigue pattern. In this same series of investigations, we are also establishing the sensitivity of these measures to the level of accuracy in which a surface electrode is relocated from one day to another or for different times in the same day. This information will be vital in establishing future protocols and interpreting our data.

Second, we are investigating the recovery process of median frequency measurements of lower back muscles following sustained fatiguing contractions. Recovery following rest periods of 1, 5, and 15 minutes are compared for control subjects. Similar tests are underway for lower-back pain patients as well.

We are targeting the first in a series of specific sub-categories of lower-back patients to be tested by our assessment technique. We are testing patients with at least a 6-month history of chronic back pain without radiographic evidence of spinal abnormalities. This group is being tested according to the same protocols for previous tests on control subjects. Variable-force, isometric contractions were added to the tests protocols to identify recruitment-decruitment abnormalities in those patients in acute pain unable to generate forceful enough contractions to elicit fatigue results. Future tests are planned for other categories of lower-back pain.

This material was presented at Independence '87, sponsored by the Veteran's Administration Rehabilitation Research and Development Service, March 1987, in Washington, DC.

Publications Resulting from This Research

Computer-Aided Back Analysis System. Roy SH, DeLuca CJ, Gilmore LD, Ladin Z, Casavant DA, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:326-328, 1987.

Low Back Pain Studies

Malcolm H. Pope, PhD; Martin Krag, MD; William Cats-Baril, PhD; Rowland Hazard, MD; Mary Moffroid, PhD; Andrew Haig, MD; Steven Reinecke, BSME; David Wilder, PhD; Jerry Weisman, MSME; Antonia Clark, MS; Janice Clements, BS
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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Vermont Rehabilitation Center (REC), now in its second five-year funding cycle, is committed to improving the prevention, treatment, and rehabilitation of low back pain through an integrated program of basic and applied research and information services. Specific objectives of the multidisciplinary center include: identification of risk factors for low back injury, pain and disability; development of new measurement methods for diagnosis and research; evaluation of treatment programs and modalities; worksite assessment and modification; service delivery; information dissemination and training. Affiliates of the Vermont REC include the New England Back Center, which operates a comprehensive rehabilitation program for chronic low back patients; and Rehabilitation Technology Services, providing service delivery to individuals with low back and other disabilities.

Projects and Progress—Several research projects are currently under way in the following areas.

1) **Prediction of Disability and Assessment of Rehabilitation Strategies.** William Cats-Baril, PhD. The REC continues its pioneering work on prediction of low back disability and construction of a comprehensive and accessible database on individuals with low back pain. Additionally, the project team aims to determine cost-benefit ratios for various rehabilitation techniques.

2) **Intervertebral Motion and Muscle Use Detection.** Martin Krag, MD. This project was designed to develop a methodology for characterizing intervertebral motion and muscle use patterns in the lumbar spine.

3) **Lifting Capacity.** Rowland Hazard, MD. Dr. Hazard has developed a prototype lifting simulator. Current research aims to evaluate the utility and reliability of the device, which promises to be a practical, reliable, and inexpensive means of determining lifting capacity for a wide range of occupational health practitioners.

4) **Exercise and Physical Conditioning.** Mary Moffroid, PhD. This project comprises several discrete studies designed to study the endurance, eccentric capability, and time to response (to postural shifts) of the muscles surrounding the lumbar spine. Long-range goals include designing effective measurement tools and treatment programs.

5) **Evaluation of Biofeedback in Lumbar Orthoses.** Andrew Haig, MD. Lumbosacral corsets are frequently prescribed for low back pain, although their effectiveness and mechanism of action have not been demonstrated. The project will compare the effectiveness of tactile feedback, trunk inclination feedback, and EMG feedback: the project comprises design and testing of devices and two triple crossover studies.

6) **Seating Studies.** Steven Reinecke, BSME. A prototype lordotic CPM device has been designed: when incorporated in a typical office chair, it provides continuous motion in the lumbar region. The goals of the present project are to refine the device and test its efficacy in minimizing back discomfort in both static and vibrational seating environments. Current seating research also includes the development of a combined sit-stand workstation. Both healthy volunteers and low back patients will be enlisted to assess fatigue, comfort, and changes in work productivity as a result of using the workstation.

7) **Vibration Studies.** David Wilder, PhD. With a long-range goal of optimizing work environments that involve vibration, the project will determine the relative contributions of various spinal support structures, seating components, and postures.

8) **Development of a Workload Assessment System.** Jerry Weisman, MSME. A Workload Assessment System is being developed to provide detailed information about various biomechanical stresses in the workplace. The system will be evaluated in numerous occupational settings.

9) **Information Services: Publications.** Antonia Clark, MS. **Public Relations.** Janice Clements, BS. The REC's Information Services Division comprises

numerous information and referral activities. Work is underway to construct a national knowledge repository, including a comprehensive bibliographic database and service directory. Information about low back pain, injury, and treatment is made available through lay and professional publications and electronic media.

Quantification of Motion Characteristics in Low Back Disorder

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Sponsors: *Ohio State University Rehabilitation Engineering Center; National Institute on Disability and Rehabilitation Research*

Progress—One of the oldest and most common disabilities facing mankind is that of low back disorders (LBD). The annual incidence rate for back injuries in the general population is over 2 percent. A recent study indicated that the annual direct and indirect costs of low back disorders was 31 billion dollars. Recent studies have also shown that industrial environments have been particularly hard hit by the problem. For example, about 25 percent of occupational injuries involve LBD and account for 30-40 percent of compensation costs. In 1980 alone these injuries resulted in 93 million lost working days.

Even though LBD's are so prevalent, there exist few reliable means to quantify the degree of disability or determine whether the patient is functionally able to return to the workplace. Patients with low back pain (LBP) usually exhibit limitations in terms of the degree of back bend they can achieve and their back motion appears extremely slow and controlled. These limitations may be related to several biomechanical sources. Therefore, assessment of trunk motion may be a key indicator of low back disability.

The measurement of spinal movement often is used as a clinical evaluative tool. Physicians note the range of bend in patients with LBP and use the degree of back bend in diagnosing and assessing the effect of therapy to check rehabilitative progress.

Marras and Wongsam (1986) used a simple sagittal plane lumbar motion monitor to evaluate both range of motion (ROM) and trunk velocity characteristics of a group of chronic low back pain patients and a normal control group. When testing the ability of subjects to perform sagitally symmetric bends, they found that trunk velocity measures were a far better indicator of disability than were traditional ROM measures.

The objective of this study is to expand the scope of that concept so that more detailed trunk motion analyses can be performed in all planes of motion of the human trunk. The different planes of motion must be tested since different musculoskeletal problems are seen when trunk motion occurs in different lines of action. It is believed that such a study will serve as a basis for a meaningful quantitative assessment method of low back disorders. Such a testing method can serve as a means to assess the degree of initial low back disorder as well as serve as a means to assess progress due to surgery, orthoses, exercise, functional electrical stimulation, and other treatment interventions.

Progress—The progress to date on this project involves the development of hardware and software components that make it possible to quantify and categorize motion components of the back. These components include variations in position velocity and acceleration profiles in every plane of the body. We are preparing to test a population of normal and LBP subjects in the coming year so that a database that associates back motion characteristics with back disorders will be established.

D. Vascular Disorders

The Role of Pressure Distribution Measurement in Diabetic Foot Care

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A319-RA)*

Purpose—The purpose of this study was to provide prospective data on foot problems in a group of diabetic veterans and to assess the role that pressure distribution measurement and footwear might play in the recognition and prevention of foot problems.

Progress—The data collection phase of the study is now complete. Data on pressure distribution, quantitative sensory response tests, foot deformity, vascular status, footwear and activity habits, ulcer and pre-ulcer incidence are currently being analyzed. The notable features of the data are that observations on several of the variables are available at 6 intervals over the 24-month period and that the patients regularly attended podiatry clinic for observation and preventative care.

Preliminary Results—In this abstract, we report the incidence of "significant events" (pre-ulcers or ulcers on the feet) which occurred in these patients during the 24-month data collection period. Pre-ulcers are defined as either of the following: 1) intraepidermal maceration (a boggy texture of the skin due to extravasation of fluid such as would be seen in an intact blister); or, 2) hematoma or callus with underlying hemorrhage. An ulcer is defined as any break in the skin which resisted healing for a 2-week period.

At least one significant event was observed in 24 of the 56 patients during the period of study. This represents an incidence of 42.9 percent. Multiple significant events were observed in 12 of these 24 patients.

In order to assess the total number of events seen, we first used the conservative approach of considering the data by lesion site. Thus, if an ulcer healed and then recurred at the same site some time later, it was considered to be a single lesion. Using this approach, a total of 54 unique lesion sites (26 pre-ulcers and 28 ulcers) were observed. Of the patients who experienced events at multiple sites, there were 5 patients with 2 lesion sites, 3 patients with 3 sites, one patient with 4 sites, 2 patients with 5 sites, and one patient with 9 lesion sites.

The second approach was to consider each new event as a new lesion, even if it was at a site that had previously ulcerated and successfully healed. Using this method, a total of 80 significant events (34 ulcers and 46 pre-ulcers) were observed. Where there was recurrence at the same lesion site, the mean duration for recurrence was 169 days (range 14–514 days, s.d. 168 days).

Future Plans/Implications—These incidence rates for significant foot events are much greater than have previously been reported. It should, however, be noted that the patients selected for this study all had vibration perception thresholds greater than 20. Thus, these data are from diabetic patients with significant peripheral neuropathy and should not be applied to the population of diabetic veterans in general. The final analysis of the database will relate the incidence of significant events to the other variables measured.

Diabetic Foot Ulcers: Quantifying the Effects of Nonsurgical Treatments

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A318-2RA)*

Purpose—We will test the hypothesis that specific medical treatments will substantially improve the rate of healing of lower extremity skin ulcers in patients with diabetes. Specific objectives are: 1) to develop an objective method to quantitate the healing progress of cutaneous ulcers; 2) to compare the rates of ulcer healing among patients randomized to receive, in addition to standard treatment, intensive diabetes management for optimal control of diabetes; nutritional supplementation with zinc and ascorbic acid; standard medical-surgical treatment alone (control); 3) to identify biomedical characteristics of patients with diabetic foot ulcers which may predict the probabilities of ulcer healing, chronic wound failure, or other definitive medical outcomes such as limb amputation; and, 4) to examine the potential utility of a novel adaptation of nuclear magnetic resonance (NMR) spectroscopy to measure noninvasively the metabolic status of ulcerative cutaneous tissue.

Volunteer patients with diabetes and lower extremity ulcers will be randomized prospectively according to a factorial ANOVA design to receive various medical treatments identified above. They will be treated and followed in the outpatient setting with quantitation of the rate of ulcer healing until total healing or other definitive medical outcome occurs. Patients will be evaluated initially by: 1) recording an extensive medical history and examination of the lower extremity ulcer; 2) laboratory determinations including measurements of diabetic control, plasma ascorbic acid, and zinc levels; 3) vascular testing including measurements of transcutaneous oxygen tension, segmental Doppler blood pressures, and toe blood pressures; and, 4) neurologic testing to quantitate neuropathy. The rate of ulcer healing will be quantitated over a defined 4-week period of treatment according to a method of tracing the ulcer contours sequentially and photography of the lesions. A subset of treated patients will be evaluated by NMR spectroscopy at baseline and during ulcer healing.

Development of a Sensory Substitution System for the Insensate Foot

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A383-RA)*

Purpose—The main objective of this research is to develop a practical sensory substitution system for the insensate foot. We are developing a system of seven sensors under each sole, which records and feeds back the information on distribution of pressure to the subject through an electrotactile display around the waist.

The engineering members of the team are John G. Webster, PhD, and Willis J. Tompkins, PhD, Department of Electrical and Computer Engineering, University of Wisconsin, Madison, WI 53706.

Progress—Bony prominences under the foot are located by inking the sole and imprinting a paper insole while walking. To minimize hysteresis, seven 12 mm diameter Interlink conductive elastomer pressure sensors are installed on metal backings in each insole of P.W. Minor Super X extradepth shoes. The sensors are calibrated with a 440-N load cell and look-up tables are stored in an IBM-PC. Raw voltage data is collected at a sample frequency of 35 Hz for 2.43 minutes. The collected data is dumped to an IBM-PC for conversion to pressure using voltage versus pressure calibration curves. The converted data is used to construct time versus pressure and center of pressure (COP) diagrams.

Results—We have now developed and tested instrumented insoles for six normal subjects and obtained patterns of pressure for them during walking, running, and with cane use. In analysis of initial data obtained in the normal studies, the most significant fact observed is that, on the average, in all subjects one leg experienced a 31 percent higher peak average COP during walking and 42 percent higher during running. The side which was loaded greater did not appear to be consistent with hand dominance. Also, it seems that during both running and walking, the highest pressure is rarely associated with either heel sensor, even in the subjects who are rearfoot strikers while running. In addition, it appears that individuals who are midfoot strikers have their COP move anteriorly and laterally during running as compared to walking.

Initial studies using this system were also done of the kinetics of cane walking. The cane was also instrumented to allow measurement of ground reactive force exerted through the cane. A standard J cane was used with trials involving the cane in both the dominant and nondominant hand. The overall magnitude of the force applied to the contralateral foot during cane-assisted walking, in comparison to unaided walking, was greatly reduced. The duration of the applied force, however, was increased by approximately one-third in both feet, as cane use slows the gait cycle. Approximately two to three times greater force was applied to the cane when used in the dominant hand, compared to the nondominant hand.

Future Plans—We have also constructed a similar system using the Hercules Model F4-4R, 100 psi capacitive pressure sensor. We will run similar tests to compare the two sensors. The medical team will identify patients with insensate feet, and run similar tests to assess pressure distributions. We will examine how pressure distribution varies with fatigue between the sensate and the insensate individual. After acquiring baseline data, we will determine the optimal method of translating sensor data to provide feedback to the patients through an electrotactile display.

Publications Resulting from This Research

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Relation of Short Foot and Tarsal Disintegration in Leprosy

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Sponsor: *Poona District Leprosy Committee*

Purpose—Over the last several years our institution has been conducting research work on tarsal disintegration (TD). While screening cases for TD, it was observed that the incidence and progression of TD in the short foot was extremely rare as compared to feet having normal length. Tarsal disintegration is a process where the tarsal bones undergo a series of slow and progressive changes, losing their anatomical configurations to each other, ultimately leading to destruction and disorganization. The typical changes observed in the established TD were not seen in the short feet. The main aim of our study was to find out the precise reason why a short foot does not undergo the typical pattern of TD, in spite of various factors such as the disease itself, secondary infection, etc., being common to both groups (i.e., patients having full length of foot and patients having a short foot).

Progress—Fifteen cases of short foot were studied both clinically and radiologically and compared with the rest of the TD cases of our series having a normal length foot. Patients having either partially or completely absorbed metatarsals were taken in the category of short foot. Their Harris-Mat prints in walking were taken and gait pattern was analyzed.

Results—The short foot presents itself clinically with superficial chronic ulceration or callosities at the distal end of the foot. There is hidden equinus with shortened medial longitudinal arch. Depending upon the severity in a normal length foot having TD, the findings were: 1) swelling and raised temperature over the talo-navicular junction; 2) bonycrepitus; 3) flattening of medial longitudinal arch; 4) pain that may or may not be present in the early stages; 5) abnormal postures of the foot in weight bearing in advanced cases; and, 6) plantar ulceration at high risk areas.

Radiologically, typical changes seen in a foot with TD were: cystic cavities, trabecular fractures, erosion or squeezing of navicular, separation of hind and fore-foot in late cases, osteomyelitis, etc. The following changes were seen in the short foot: intact tarsal bones, slivers of metatarsals, signs of hidden equinus, increased radio density in the anterior pillar area, and relatively osteoporosed calcaneum, because of the altered weight bearing pattern.

Harris-Mat pattern revealed flattening of medial longitudinal arch in cases having TD where there was distal pressures and a shortened medial arch in short feet.

When the gait pattern of a short foot is studied, it is observed that because of the short lever the balance becomes critical. This leads the patient to taking short steps. The weight bearing area remains the same for every step involving a minimal generation of forces. Absence of classical push-off, shortening of the effective length of medial longitudinal arch, and the absence of transverse arch in a short foot results in a considerable overall reduction in the shearing forces.

The role of shearing force, in a neuropathic foot thus seems to be of significant value in the progression of TD. These forces get considerably reduced in a short foot due to loss of heel-toe pattern, reduction of ankle movements, and a short stepping gait that prevents TD.

Retrospectively, on the same lines, we have successfully treated cases of TD with a Fixed-Ankle Brace (FAB) which, because of its rocker action with resulting reduction of forces, abolishes the heel-toe pattern by controlling ankle movements.

Malignant Transformation in Plantar Ulcers in Leprosy

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Sponsor: *Poona District Leprosy Committee*

Purpose—The occurrence of plantar ulcers in the foot is a major obstacle in the rehabilitation of leprosy patients. Chronic non-healing ulcers, especially if subjected to repetitive trauma, are predisposed to malignant changes. Moveover, exogenous chronic osteomyelitis a common sequelae to plantar ulceration, is also known to be a predisposing factor for skin cancer. It is surprising then to find only a few reports of carcinomata arising in leprous plantar ulcers, although leprosy has been known to mankind for thousands of years. The aim of our study was to find out the incidence of carcinoma in neuropathic ulcerated feet, the tumor behavior, correlation between chronicity and the occurrence of carcinoma if any, and to plan the treatment accordingly.

Progress—Twelve leprosy patients admitted to Dr. Bandorawalla Leprosy Hospital from the years 1981 to 1987, with cauliflower growth or ulcers proved by biopsy as squamous cell carcinoma on the foot, were included in this study. Out of these, ten were males and two were females. Their ages ranged from 35 to 65 years.

Ten cases had carcinomatous change in the ulcer over plantar aspect. One case had an ulcer on the lower leg and dorsum of the foot, and another over the lateral malleolus showing malignant changes. Out of ten plantar ulcer cancers, six were on the heel and four on the forefoot.

Eight cases were borderline tuberculoid and four were borderline lepromatous. Duration of

best copy available

ulcers ranged from two to 16 years. All cases presented with secondary infection and regional lymphadenopathy. Three cases presented with advanced disease with fungating regional nodes and were fatal. Nine cases were amenable to surgery and underwent below-knee amputation.

Results—Almost all cases presented with cauliflower growths, only one presented as an excavating endophytic growth on lateral malleolus and one as an ulcer with everted margins on the lower leg and dorsum of the foot in a typical phagedenic or tropical ulcer.

Nine out of 12 patients presented with pain as a prominent symptom. This was probably so because the deep sensations in anaesthetic feet of leprosy are intact, and the deeper malignant infiltration might have been responsible for the pain.

There was no correlation between the type of leprosy and occurrence of ulcer cancer. It seems that behavior of cancer is more aggressive in lepromatous types. Three out of four cases in this category presented with regional lymph nodal metastases, though histologically all were low-grade, squamous cell carcinoma.

There also was no correlation between chronicity of ulcer and occurrence or spread of cancer. Thus, some ulcers were present for two to three years before they turned malignant, and some took 16 years for the same.

Ulcer cancer was seen more on the hind foot, but the forefoot was not spared. In our series, six were heel lesions and four were forefoot lesions. It seems that the incidence of heel ulcer cancer is high. Ulcer cancers were almost always secondarily infected and had concomitant chronic exogenous osteomyelitis. All presented with regional lymphadenopathy.

As a definitive treatment, below-knee amputation was carried out and lymph nodes were observed, which usually subsided after removal of the infected primary. If they persisted, a regional block dissection was carried out.

All leprosy patients, even those with bad foot ulcers, must wear protective footwear to avoid external irritation, and chronic osteomyelitis must be brought under control by prompt surgical measures.

XIII. Head Trauma and Stroke

Hemi-Neglect Syndrome: Visual Scanning and Reading Skills Retraining

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C522-RA)*

Purpose—The purpose of this project is to determine the efficacy of perceptual remediation (PR) in a well-controlled study of right hemisphere stroke patients with left hemi-neglect (LHN). Disability following stroke is a major public health problem in terms of health care costs, loss of income, and impaired quality of life. Between 35 and 70 percent of patients with right hemisphere brain damage (RBD) manifest LHN: a multi-modal failure to attend to stimuli in the left side of space. The deficits associated with LHN interfere with behaviors which require full-field attention to the environment, including reading and writing, walking, and navigating in a wheelchair. LHN may occur either with or without sensory deficits. The syndrome frequently includes anosognosia (i.e. lack of awareness of deficit), which further compromises functioning and militates against participation in rehabilitation programs. There is a degree of spontaneous recovery of some severe perceptual deficits of LHN, but residual deficits continue to impair functioning.

A model for remediation of perceptual deficits of RBD patients, with an emphasis on defective visual scanning, was developed at the Institute of Rehabilitative Medicine (IRM) at New York University. The model involves systematic retraining of patients in effective strategies for visual scanning, and for organization and sequential analysis of spatial information. However, there is very little data on the efficacy of remediation programs based on this model. Those reports which have been published either are uncontrolled or compared a PR sample to a sample which received standard occupational therapy without PR.

Recently, many PR computer systems, which purport to be based on the IRM model, have become commercially available. However, many of these systems simply provide patients with practice on visuo-spatial tasks, without guiding the development of compensatory visual scanning strategies. There is no published data on the efficacy of remediation using these commercially available systems. There is a need for solid research to determine the efficacy and essential components of PR treatment for RBD patients with LHN.

Over the last five years, co-principal investigator Leonard Price has developed a microprocessor-based computer system which builds on the IRM model for PR. Pilot data suggests that patients who receive PR using this system do improve on perceptual and cognitive tasks. However, the pilot data suffers from the problems discussed above, and does not indicate whether these patients would have improved equally with other interventions.

Central Motor Tract Testing After Recently Completed Stroke

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B453-RA)*

Purpose—This project proposes to study magnetic stimulation of the motor cortex as a method for assessing central motor tract function in the stroke patient. The technique involves stimulation of de scending motor fibers in the brain through the use of a large, short-duration magnetic field. This induces muscle contraction in a contralateral extremity. The time between stimulation and resultant muscle action potentials, when corrected for peripheral conduction time, is known as the central motor conduction time (CMCT). This procedure provides quantitative electro-physiologic information that will be useful in the management and rehabilitation of stroke patients. It may also help us understand the neurophysiology of motor recovery after stroke.

Our initial key questions are: Do CMCT's correlate with other measurements of motor function, and can CMCT's predict the prognosis for motor recovery after stroke? Our first short-term objective will be the measurement of CMCT's in an age-matched control population. This will be followed by a prospective study of stroke patients with measurements of CMCT's, strength, and disability scores at 1 and 5 weeks after onset of symptoms. To test the prognostic value of this measure, we will attempt to predict the outcome in a second prospective study of stroke patients.

Our first long-term goal is to compare alternative methods of stroke rehabilitation, using CMCT's as a monitor of motor recovery. We expect to eventually extend our research to the acute management of stroke and the study of other lesions in central motor tracts.

Effects of Thermal Stimulation on Dysphagia After Stroke

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C485-RA)*

Purpose—This study's major goal is to measure the effects of thermal stimulation on a variety of oropharyngeal swallowing abnormalities, including delay in the pharyngeal response, in patients who have suffered multiple cerebral vascular accidents (CVA). Other goals are: 1) to determine the prognostic significance of patient response to thermal stimulation during baseline testing; and, 2) to examine correlations between treatment effects and sites of lesion, severity of pharyngeal delay, severity of overall neurologic deficit, nutrition, and patient/caregiver assessment.

The major dependent variables are scintigraphy, videofluoroscopy, manometry, and electromyography during liquid swallows. Scintigraphy will provide quantification of the boluses' passage through the mouth and pharynx. Videofluoroscopy will allow analysis of duration and range of tongue, velar, and laryngeal movements. Manometry will provide data on lingual, pharyngeal, and upper esophageal segment pressures. Manofluorography will measure the relationships of movement and pressure changes. Electromyography of the mylohyoid muscle bilaterally will provide data on that muscle's timing in relation to movements and pressures. Other measures used to interpret responses to treatment will include: 1) baseline and follow-up magnetic resonance imaging; 2) serial neurologic examinations; 3) serial weight-taking, dietary histories, and calorie counts; and, 4) serial assessments of swallowing by patient/caregiver.

Methodology—The study design is a combined multiple baseline across subjects for matched patient pairs, with a withdrawal feature added for additional experimental control. This design will be replicated across approximately 15 patients/year for 4 years. Acute and chronic stroke patients who meet neurologic criteria, including proof of at least two CVA's, will be given 6 baseline swallows, 3 without and 3 with thermal stimulation, as measured by videofluoroscopy, manometry, and EMG. Three additional swallows will be evaluated with scintigraphy. Patients experiencing delay will be grouped into matched pairs based on the site of the lesion. One member of each pair will be enrolled in 5 days of thermal stimulation and then retested. Thermal stimulation will be withdrawn for 5 days, followed by retesting. Treatment will be reintroduced for 5 days, and the patient will be retested. Treatment will again be withdrawn for 5 days, and the patient will be retested.

The other patient in each pair will begin thermal stimulation after a 5-day delay and a second progress test. Treatment will then be withdrawn for 5 days. The patient will be retested. Again, 5 days of treatment will be followed by retesting. These treatment/no treatment periods will be counterbalanced within each patient pair. All patients will receive 1-month follow-up evaluations. Data will be analyzed by visual display and visual inspection. Correlated test and repeated-measures analysis of variance will also be performed. If a sufficient number of patients complete the study, a multivariate analysis of variance will be performed. Social validation will be accomplished by analysis of treatment effects on diet variables and the patient/caregiver questionnaire.

Development of an Outcome-Oriented Head Injury Database

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Sponsor: *Center for Disease Control*

Purpose—From among the millions of head injuries that occur each year, thousands of individuals survive to face significant physical, cognitive, and emotional difficulties associated with recovery. Unlike physical problems, cognitive difficulties do not necessarily diminish with time. At present, it is unclear which head-injured persons with residual cognitive deficits are most likely to benefit from extensive professionally-directed care, as there is no consensus as to what the "average" severely head-injured person is able to do, given a specific time post-onset. The objectives of this project are: 1) to develop a transportable rehabilitation outcome-oriented head injury database; 2) to document the natural history and clinical course of this disorder; and, 3) to facilitate rigorous comparison of various management and rehabilitation strategies.

Methodology—After review and evaluation of existing head injury data collection protocols and procedures, and an extensive head injury literature review, we will develop a list of demographic, acute care, and follow-up variables to be included in the database. Variables will be defined and collection procedures detailed in an instructional syllabus. Computer programs will be written for data entry, quality control checks, error detection, and management reports.

Preliminary Results—Existing head injury protocols and data collection instruments from institutions across the country have been collected and evaluated. A data collection syllabus has been developed and contains 176 variables on demographics, acute care, and follow-up care. Data collection instruments and guidelines have also been developed. Pilot data has been collected on 98 patients and variables have been revised and/or deleted as needed.

Future Plans—A reliability study will be completed and the syllabus, data collection instruments, and guidelines revised accordingly. Efforts are currently underway to cooperate with the five federally-funded Model Traumatic Brain Injury Care Systems in the development of their national database. We plan to dovetail our efforts in the development of our outcome-oriented database with these systems, so that the collection of head injury data will be as standard as possible across the country.

Early Intervention with Globally Aphasic Stroke Patients Using a Computerized Visual Communication Technique

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project undertakes the controlled testing of a computerized visual communication technique as an early intervention directed at recovery of language function in severe global aphasia after stroke. The technique provides for mouse selection of "cards," on which line drawings are displayed, in accordance with objects presented for matching. Advanced stages in the training protocol involve matching after delay, and matching and clicking cards into place in a message-building area. The methodology is a large-sample, controlled, longitudinal, randomized group study.

Progress—Software has been developed which presents cards on a full-page display monitor, with task parameters specified by the trainer in keeping with the experimental protocol and the subject's performance. At the same time, instructions, alerts, and the current status of task parameters are presented to the trainer on the Macintosh computer's own screen. The program reinforces each successful trial, and fails to respond when incorrect selections are made. Parameters which can be varied include position on the screen of each card in the response field, number of options in the response field, number of stimuli presented at one time, time interval after which a failure to respond will be recorded, and criteria for successful completion of each level and for failure at a given level, resulting in a return to guided practice. Tasks can also be designed so that specific cards are made to appear in specific locations.

Results—Using Reflex for the Macintosh, a database system has been designed to store data acquired by the program. Data stored includes the number of trials to criterion at each level, and the number of practice tasks. Response data include correctness, response choice, response latency, location on the screen of selected responses, reflecting any spatial bias or preference, and semantic category membership of responses, reflecting any differential success with items from different categories. Also noted is the path of the cursor, i.e., the amount of time the cursor spends in various windows on the screen before the response is chosen. Language status is assessed prior to the intervention, at its completion and at a 6-month follow-up.

Subjects for this study are patients within 2 weeks of a left cerebral vascular accident (CVA), who receive a score of 2 or worse on the Boston Diagnostic Aphasia Examination severity scale, and who have virtually no auditory language comprehension. Subjects are randomly assigned to an experimental or control group, with patients in the latter category spending an equivalent amount of time using available language software.

Implications—It is hypothesized that participants in the experimental intervention will show more rapid recovery and attain better levels of recovery than control group members. Preliminary tests of the feasibility of the intervention with 10 patients indicate that some level of accomplishment is achievable for most of these severely impaired patients.

Predictors of the Resolution of Hemispatial Neglect and the Efficacy of Treatment Interventions

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this study is to investigate the relative contribution of *in vivo* pathophysiological markers and neuropsychological variables as predictors of the resolution of hemispatial neglect during the first year after stroke. The differential impact of these factors on natural recovery and on the efficacy of treatment intervention will be examined. Physiological status will be assessed by somatosensory and cognitive evoked potentials and neuropsychological factors will include severity of hemispatial neglect, arousal/attention, abstract reasoning, memory, and verbal functioning. The results of pilot studies have highlighted the importance of the patient's awareness of the perceptual deficit as a predictor of recovery from hemispatial neglect. Awareness may be integrally related to other relevant factors in treatment response, such as compliance and the ability to use compensatory strategies.

Overall patterns of recovery of visual-spatial functioning have been examined, and treatment programs targeted to these deficits have been shown to be effective in overall group designs. However, there is tremendous individual variability in treatment response, and our goal is to examine specific individual predictors of recovery and treatment response.

Progress—We have developed a reliable measure of verbal awareness of cognitive deficits. Forty (RBD) stroke rehabilitation inpatients with moderate to severe levels of hemispatial neglect were randomly assigned to either a control ($n = 13$), or to one of two treatment conditions for visual-spatial deficits. In the Depth condition ($n = 12$), patients were exposed to overlearning trials or a narrow array of visual-spatial tasks. In the Breadth condition ($n = 15$), patients were exposed to less consistent but more personally relevant tasks also designed to enhance compensatory visual scanning behavior. All patients were rated on level of awareness of deficits prior to treatment. Awareness of deficit was assessed by first asking patients to relate their main difficulties and then specifically probing for changes in thinking, concentration, or perception. Responses were recorded verbatim and blindly scored on a 5-point rating scale to indicate awareness of deficit. The reliability for data from three independent raters was $rkk = 0.96$; $rcc = 0.88$.

Regression analyses were conducted for each group to predict changes in test score performance on four measures of visual-spatial functioning. These dependent variables were change scores on the following measures: Letter Cancellation, Wide Range Achievement Test (WRAT Reading), Line Bisection, and Raven's Colored Progressive Matrices (RCPM). The independent variables entered in the equation to predict change scores were: hemianopic field defect rating, level of depression, the Beck Depression Inventory (BDI), WAIS-R Similarities, Conceptual Level Analogy Test (CLAT, a measure of abstract reasoning), and the Awareness of Deficit measure. Of these predictor variables, only the level of awareness of deficit was consistently related to improved performance in the visual-spatial domain. High initial awareness of deficit was a significant predictor of improved functioning on psychometric tests across all three patient groups.

The finding that level of awareness predicted improvements in visual-spatial performance is remarkable in that prior efforts to identify individual factors accounting for differential outcome have failed to yield meaningful findings. The predictive power of this awareness of deficit measure is highlighted by the results of a second set of regression analyses in which this awareness of deficit measure was the only significant predictor of functional outcome, as indexed by ambulation status, at 5-month follow-up. This regression equation also included a motoric impairment score, a hemispatial neglect measure, and a measure of general orientation. It is of particular note that the motoric impairment score was *not* a predictor of follow-up ambulation status, and awareness of deficits *did* account for a significant proportion of variance in this outcome measure.

The New York University (NYU) Head Injury Family Interview: A Multi-Center Study

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The *NYU Head Injury Family Interview* (HI-FI) was developed and piloted as part of the previous NIDRR-sponsored Research and Training Center on Head Injury and Stroke at NYU Medical Center. The most current version of the instrument (Version 1.2) consists of a *Demographic and Pre-Injury Form,* and four interviews: the *Follow-up Interview,* the *Survivor Interview,* the *Significant Other Interview,* and the *Impact on the Family Interview.*

HI-FI was developed because of the need for a structured interview, serving both research and clinical purposes, which would allow for systematic collection of the kind of data not obtainable from standard neuropsychological testing. Such data include the subject's and family's perception of the range of problems, severity of problems, relative impact of different problems on the family, coping strategies, change in activities of daily living (ADL) capacities, social activity, involvement in home activities, utilization of professional and community services, and successes encountered in attempts to return to work and/or school.

Methodology—The interviews consist of open-ended questions which are administered first, so that responses are not primed by specific checklist items. Open-ended questions proceed from general to specific for the same reason. Much of the information from the interview can be coded for computer entry and data analysis. The interviews can be administered by a professional of any discipline sensitive to the issues in head trauma rehabilitation. Parts of the interviews can be self-administered.

The instrument will be field-tested at a number of collaborating centers across the country. By field-testing, we will be able to amass a larger database to allow statistical procedures not possible with small-sample piloting, and, in addition, collect feedback on content areas among diverse users to refine the instrument.

Collection of information on traumatic brain injured patients (TBIs) and families will be across a diverse group of people at different points in time post-injury. In addition, we will look at the relationship of HI-FI data with other information such as demographics, time since injury, and extent of rehabilitation. It is our ultimate goal to revise, refine, and gather a statistical database for the instrument, write a manual, and disseminate the instrument for professional use on a wider basis.

Progress—We currently have four centers, in addition to the NYU Medical Center, participating in the Multi-Center Study. These centers are: Braintree Hospital-Traumatic Head Injury Program, Hahnemann Rehabilitation Center Head Injury Service, The Institute for Rehabilitation and Research in Texas, and Marionjoy Rehabilitation Center. These centers are currently using the HI-FI in their outpatient rehabilitation services and sending copies back to NYU for computer entry. A few times a year, each center will receive a statistical summary of results regarding their own sample and the entire sample collected to date.

Future Plans—We will ask all participants to provide us with feedback on the use and content of the instrument through a feedback form which will be provided periodically. We plan to continue to collect data from these centers through 1989. The following year will consist of data analyses, and major revisions of the instrument based on statistical findings and feedback from the users. A manual will be written for the revised instrument and the NYU Head Injury Family Interview will be packaged and disseminated for professional use.

Minor Head Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Minor Head Injury (MHI) can be defined as head trauma that results in loss of consciousness of 20 minutes or less, no focal neurological abnormalities, no mass lesions, and hospitalization of 48 hours or less. MHI accounts for 85 percent of all hospital head injury admissions, and up to 95 percent of all persons who seek medical attention after trauma to the head.

These patients have no physical disability and are not referred into the rehabilitation system. They are discharged directly home from the acute care hospital with the implicit or explicit message that they are "OK," and can gradually return to work or school. Yet clinical and research evidence suggests that up to one-third of these patients suffer neuropsychological deficits in the areas of attention and concentration, learning and memory, and the speed and capacity of information processing, that interfere with their ability to return to premorbid levels of functioning. Their recovery is complicated both by the psychological overlay resulting from failure, frustration, loss of confidence, and diminished self-esteem, and by an interaction with premorbid personality factors.

These patients often show up in neurological, rehabilitation, or mental health clinics complaining of functional disability and subjective symptoms, but lacking concrete neurological deficits. Standard neuropsychological evaluation is often insensitive to the subtle but significant breakdowns that occur following MHI. It is not clear what program of intervention is effective in either preventing or reversing functional disability following MHI.

Progress—Core Area IV of the NYU Medical Center's Research and Training Center on Head Trauma and Stroke contains four research projects in the area of Minor Head Injury. The aims of these studies are to: 1) document the incidence of functional disability among patients seen in the emergency room (ER) after MHI, but not admitted to the hospital, and the factors identifying patients at risk; 2) develop neuropsychological tests more sensitive to the breakdowns in cognition that occur after MHI, focusing on dual or split attention tasks; 3) identify the variables that contribute to functional disability in MHI patients who appear neurologically normal including neuroanatomical, electrophysiological, neuropsychological, and personality variables; and, 4) evaluate the effectiveness of progressive interventions in preventing and reversing functional disability following MHI.

Methodology—The projects currently being carried out are: 1) A longitudinal study of all patients seen in a major city hospital ER following TBI who are not admitted to the hospital; 2) Development of innovative neuropsychological tests that measure split attention, and utilize variations on cortical evoked potentials (P300's) to document electrophysiological correlates of breakdowns in complex attention in MHI; 3) A multimodal study of MHI patients who have normal CT scans but complain of being unable to function after their injury. Measures include Magnetic Resonance Imaging, Cortical Evoked Potentials, EEG, motor control tasks, neuropsychological evaluation, and personality measures. Orthopedic and peer control groups are utilized; and, 4) A stepwise neuropsychological rehabilitation intervention with MHI patients, including early evaluation, education and feedback, individual counseling and remediation, and group interventions.

Psychological and Social Adjustment After Stroke

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Purpose—The repercussions of a stroke on both the stroke patient's, and his/her family's lives go far beyond purely physical and health-related issues. Research has demonstrated increased depression and psychiatric symptomatology, decreased socialization and leisure activities, and increased use of medical services in both patients and their families after a stroke. Decreased psychosocial functioning may exist independent of severity of neurological and physical deficits. Many patients and their families are unprepared for the pervasive and persistent stresses of dealing with the changes brought about by a stroke. Cognitive and affective changes are particularly difficult to cope with and understand. Additionally, efforts to alleviate adjustment difficulties by the provision of information soon after the stroke may have limited use as both patient and family members need time to adjust to the exigencies of their situation before new information can be taken in. Younger stroke patients face particular difficulties in that their stroke occurs at a stage in the family life cycle which is out of phase with standard expectations of retirement, dependency, or caregiving.

Progress—To address the needs of this population, a psychosocial intervention was designed for younger stroke patients (age 45 to 54) and their families. The objectives of the intervention are to enhance patient and family cooperation with in-patient rehabilitation, and to enhance the psychosocial adjustment of stroke patients and their families in the 5-6 months after discharge from an in-patient rehabilitation facility.

Methodology—A treatment program will be provided which will address cognitive deficits, patient and family understanding of the implications of cognitive deficits, and aspects of interpersonal functioning (family and social) which may be affected by the stroke. At the in-patient phase, treatment will concentrate on education of patient and family members regarding the nature of stroke and related cognitive, perceptual, and affective changes. Feedback will be provided on the basis of an initial neuropsychological and psychosocial assessment. Following discharge from the in-patient facility, treatment will be continued on an outpatient basis in the patient's home. Treatment will be provided by a "personal coach" who will tailor a program of cognitive and perceptual remediation to the patient's specific needs. The personal coach may also address the patient's social behaviors and use of leisure time, and assist in the establishment of adequate social resources for caregivers to obviate caregiver strain. The coach will also intervene when interpersonal problems among family members result from well-intentioned, but inappropriate helping strategies. Periodic clinical, neuropsychological, and psychosocial assessments will guide the targeting and delivery of the treatment program. Family interventions will be delivered in accordance with the Solution-Focused Model of brief family treatment.

Outcomes will be evaluated by assessments administered just prior to discharge from the hospital (in-patient phase) and at the end of the treatment program (5-6 months post-discharge). Patient outcomes will be assessed by measures of cognitive and perceptual functioning, activities of daily living (ADL), mood, satisfaction with family and social support, social functioning, use of leisure time, and vocational status. Family (caregiver) outcomes will be assessed by measures of mood, caregiver burden, and social adjustment.

Cerebral Ischemia and Monoamines

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Sponsor: *National Institutes of Health*

Purpose/Progress—The relationship between the failure of energy and the disturbances in monoamine metabolites was investigated in the brain of Mongolian gerbils subjected to bilateral ischemia only (5 or 15 min) or with 1 hour reflow. The use of microwave irradiation to fix the brain allowed the measurement of labile metabolites and neurotransmitters from the same sample of tissue.

Results—Both the energy charge and the content of ATP and P-creatine were reduced to the same extent in the hippocampus and striatum at 5 min and 15 min of blood supply-deprivation to the brain while the changes in monoamines were only found after 15 min of ischemia. On the other hand, in reflow, the energy charge and the immediate source of energy recovered almost completely in these structures, whereas the changes in the content of the monoamines were not only present but the level of NE was also reduced in recirculation after 5 min ischemia.

Implications—These results clearly demonstrate that the changes in the tissue energy charge are not directly associated with the disturbances of cerebral amines in ischemia.

Epidemiology of Cerebrovascular Disease in Adults

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Sponsor: *National Institutes of Health*

Purpose—This investigation is aimed at: 1) evaluating the effect of heart disease and hypertension as potentially treatable precursors of completed stroke and transient ischemic attacks; 2) documenting unusual patterns of cerebrovascular disease; 3) determining the autopsy patterns for patients dying with cerebrovascular disease in a defined community; and, 4) examining if weather parameters have any effect on stroke incidence.

Transient Ischemic Attacks (TIAs) in the Experiment Gerbil Model

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Sponsor: *National Institutes of Health*

Purpose—The experimental model for transient ischemic attacks (TIAs), developed in gerbils, represents the first model that can be used in an easy, reproducible way to systematically study various aspects concerning the effect of repeated ischemic attacks upon brain tissue.

Results—Our observations, using this model, indicated that there is a cumulative effect of repeated ischemic insults, when they are carried out at time intervals at which there is post-ischemic hypoperfusion. The cumulative effect of repeated ischemic insults is expressed in intensity of edema and brain tissue injury, which in three repeated insults is considerably higher than that from a single ischemic insult of duration equal to the sum of the individual repetitive attacks.

Physiological Analysis of Voluntary Movement

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Sponsor: *National Institutes of Health*

Purpose—Studies in the Gait Laboratory of the Department of Rehabilitation Medicine have focused on the control of balance. Simultaneous measurement of body angles, foot-floor forces, and multiple EMGs are possible. Studies in normal subjects have revealed insights into the biomechanical effects of postural muscle activity. Similar studies have been initiated in patients with cerebellar disturbance and Parkinson's disease.

Results—In patients with Parkinson's disease, there was a positive correlation between circulating levels of dopamine and cognitive motor capabilities in a choice-reaction-time situation, but not in a simple reaction-time situation. In normal subjects, triggered muscle responses produced by stopping voluntary movements were similar to muscle responses generated when subjects initiated a voluntary movement from the stopped location, thereby suggesting that triggered and voluntary reactions are mediated by similar central nervous system mechanisms.

Future Plans—The study of motor control in hemiplegia is being planned and apparatus prepared. Patients with discrete brain lesions will be studied; patients with strokes will be the main group, and many patients will be followed serially from onset of the disorder to recovery. Preliminary studies with positron emission tomography (PET) of normal subjects have shown that it is difficult to identify cortical areas active with voluntary movement using fluoro-deoxy-glucose (FDG) as the tracer. Further studies are planned with oxygen-15-water which will probe blood flow rather than glucose metabolism.

Stroke and Trauma Program Phase I-II Studies of Stroke Therapies

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Sponsor: *National Institutes of Health*

Progress—This project includes all aspects of data coordination and management for studies of interventional therapies for stroke initiated by task orders issued under the aegis of the DST Master Agreement. Currently seven studies, each with two to three clinical centers, are in various stages of operation. A dose-escalation study of Naloxone with acute cerebral ischemia has been completed, and the base for maximum tolerated dose, toxicity, and adverse effects were established. A Phase II study of Naloxone was also completed, and analysis files have been constructed. Data collection for a pilot study of the benefits of hypervolemic hemodilution (DEXTRAN-40) for the treatment of stroke-in-evolution has also been completed.

A dose-escalation Phase II study of Nicardipine, a calcium channel blocker, for the prevention of vasospasm following subarachnoid hemorrhage, and Phase II studies of Heparinoid, Nicardipine, and rt-PA for the treatment of acute cerebral ischemia are ongoing. Patient accrual and data collection for these studies will be completed shortly.

Ischemic Brain Edema 5-HT Receptors

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Sponsor: *National Institutes of Health*

Purpose/Methodology—Attenuation of kinetic properties of 5-HT (serotonin) S2-receptor (3H-Ketanserin) binding sites has been detected in tissue homogenate and synaptosomes of cerebral cortex in ischemic edema. The changes were found at the time of greatest accumulation of tissue water and increased 5-HT release in the brain of gerbils subjected to bilateral carotid artery occlusion for 15 min and 1 hour release. To elucidate further the pathomechanism of cerebral ischemic edema and its association with changes in the 5-HT metabolic pathway, we investigated the properties of 5-HT(1A + 1B) and 5-HT(1B) receptor binding sites in the same model. Tritiated 5-HT in the presence of cold 5-HT served to detect 5-HT(1A + 1B) binding sites, while the addition of spiperone permitted the demonstration of 5-HT(1B) binding sites in synaptosomes of cerebral cortex.

Results—A significant reduction of 5-HT(1A + 1B) and 5-HT(1B) binding sites was seen in the cerebrocortical synaptosomes obtained from brains subjected to ischemia with and without reflow. In addition, the affinity of 3H-5HT for 5-HT(1B) binding sites was increased as compared to controls. The kinetic changes in 5-HT(1B) binding sites suggest a presynaptic modulation of 5-HT autoreceptors to be present beside an altered function of post-synaptic 5-HT receptors (5-HT[1A + 1B] and S2-receptors) in ischemic brain edema.

Stroke Data Bank

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Sponsor: *National Institutes of Health*

Purpose—The Stroke Data Bank is a prospective observational study collecting data on hospitalized newly-diagnosed stroke patients at four clinical centers. The four collaborating clinical centers are responsible for the collection of acute care and longitudinal follow-up information using common definitions and procedures, under contracts NO1-NS-2-2302, 2398-9, NO1-NS-5-2384.

The general objective for the project is to provide a large and comprehensive body of data for clinical research on the factors influencing survival, morbidity and quality of life following onset of a stroke. The BFSB serves as the statistical coordinating center for the project, providing an on-site front-end data entry system with interactive feedback for data editing; the database management system for transmission, storage and retrieval of data, for monitoring of data acquisition and its quality; and for statistical collaboration with the clinical investigators for the analysis of the primary research questions.

Progress—The project has completed its fourth and final year of data collection and has entered 1,805 patients as of September, 1986. The first major analyses began after accrual of patients was completed (September, 1986) and the acute care data was entered and edited. A mathematical model for identifying patients at greatest risk for progression of stroke has been developed based on the Pilot Stroke Data Bank (SDP), validated and revised, based on the Main Phase SDB. The characteristics of the diagnostic subtypes of lacunar and infarcts of undetermined cause have been examined in detail.

Mathematical models for both infarcts and intracerebral hemorrhages have been developed to identify patients unlikely to survive for one month following their stroke. Patient and lesion characteristics detected on CT scan that are associated with silent or unreported old strokes have been identified.

Statistical Studies on the Stroke Data Bank

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Purpose—This project currently includes three studies, each of which is a component of the Stroke Data Bank or its precursor, the Pilot Stroke Data Bank. The studies are: 1) *Evolving stroke.* Using demographics, history, clinical and laboratory data, this study describes the temporal course of stroke-in-evolution and attempts to identify factors that cause or contribute to evolution. 2) *Prognostic factors for 30-day mortality.* Multiple logistic regression models, one for ischemic stroke and another for intracerebral hemorrhage, were used to determine prognostic factors for 30-day mortality. Logistic models were derived using data from the pilot project: 620 ischemic strokes with 52 deaths, and 94 intracerebral hemorrhages with 32 deaths. Potential risk factors (112 in all) were initially screened by univariate statistical methods and those screened positive were examined multivariately in the logistic model. These derived models will be cross-validated by examination of their predictive ability on data from the current Stroke Data Bank. 3) *Discrimination between intracerebral hemorrhage and ischemic stroke.* This study identifies factors, excluding CT information, available shortly after stroke onset that provide optimal classification into the two diagnostic categories.

An Examination of Multiple Cause of Death Data for Stroke

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Sponsor: *National Institutes of Health*

Purpose/Methodology—This project has three main goals. The first goal is to determine whether a change in the coding of a stroke on death certificates as underlying, versus as an associated, cause of death is partially responsible for the large decline in the rates of stroke mortality as calculated from the underlying cause of death. Next, to construct life tables and approximate the impact of eliminating stroke as a cause of death; and lastly, to examine the pattern of multiple causes of death which occur from stroke. Computer tapes, issued by the National Center for Health Statistics, containing all death certificates in the United States for the period 1968-1978 were used. All certificates where stroke (ICDA-8 Codes 430-438) was listed as underlying or associated cause of death were selected for study. The data were then tabulated by age, race, and sex. Life tables were constructed to estimate the change in life expectancy if stroke was eliminated as a cause of death. An examination of disease pairs (underlying and associated) was also undertaken.

Evaluation of Electrical Impedance in Cerebral Ischemia

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Sponsor: *National Institutes of Health*

Purpose—The effect of duration of ischemia on impedance in the caudate and cortex have been extensively studied in the cat, and correlated with cerebral blood flow, and edema, as well as other physiological parameters.

Results—It was found that when the cerebral blood flow was reduced to values below about 12 ml/100gm/min, the cerebral impedance increased quickly within about 3 minutes to 150 percent or more of the pre-ischemic value. The magnitude of this rise was variable, but the course was characteristic. After about 10 minutes, the impedance rise leveled off to a plateau value. Upon release of the occlusion, the impedance rise leveled off to a plateau value. Upon release of the occlusion, the impedance fell within a few seconds towards pre-ischemic values. For short durations of ischemia (less than 10 minutes) the impedance fell to pre-ischemic values. For somewhat longer durations (about 20 minutes), the post-ischemic impedance values were significantly less than the pre-ischemic values. Confirmation that this lowered impedance was indicative of edema was found in lowered specific gravity of the brain tissues.

Longer ischemic durations (one hour, and up to three-hour durations) showed much variability in the course of post-ischemic impedances. However, all were found to be severely edematous by gravimetric analysis, and showing severe leakage of Evans blue dye through the blood-brain barrier. In some instances, a secondary rise in impedance appeared several hours after release of the occlusion and were believed to reflect a compression of the brain by edematous swelling. The relationship of changes in impedance to ischemia is not yet clear. Further study is planned.

Study of Cerebral Electrical Activity Associated with Ischemia

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Sponsor: *National Institutes of Health*

Purpose—Our purpose is to perform a study of the electrophysiological manifestations of ischemic damage to functional activity. It is expected that the initial focus of effort will be on the recovery of electrical activity following temporary ischemic insults of graded durations.

Progress—Since initiation of this project, instrumentation has been procured and installed but collection of experimental data has not commenced.

The Measurement of Cerebral Blood Flow by Laser Doppler Velocimetry

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Sponsor: *National Institutes of Health*

Purpose—A study was made of cerebral blood flow (CBF) in gerbils by Laser doppler velocimetry (LDV).

Results—Each animal was subjected to 5-minute bilateral carotid occlusions each hour for 3 hours. Continuous measurement of CBF was made of the parietal cortex through the cranium. There was excellent consistency and repeatability from gerbil to gerbil. The essential features were: the CBF as revealed by laser Doppler velocimetry (LDV) dropped to zero during ischemia, arose upon release of ischemia to a value slightly above the preischemic value, then declined to a much lower value over the hour before the next occlusion. There was no evidence of an accumulative effect with respect to the ischemia.

Study of Oxygen Tension Change Associated with Ischemia

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Sponsor: *National Institutes of Health*

Purpose—Using polarographic electrodes, oxygen tensions were measured in the cerebral cortex of gerbils subjected to repeated ischemias of short duration.

Progress/Results—In controls before ischemia, the cortex pO_2 values were found to vary from about 55 to zero tor. These variations did not seem to correlate with depth or topographical location. When this data was assembled into a bar histogram of frequency of particular O_2 tensions, the distribution was Gaussian-shaped, with its mean in the 20-25 tor interval.

When the animal was made ischemic by bilateral carotid artery occlusion, the pO_2 dropped rapidly to zero, reaching this value in about 3 seconds. The dynamics of the recovery of the pO_2 was dependent on the duration of ischemia. Very short duration ischemias of a few seconds were followed by immediate recovery of pO_2 in a few seconds.

For longer durations of ischemia (up to one minute), the pO_2 level recovers promptly with some overshooting. The pO_2 level rises above the preischemic level by as much as two-fold. With still longer durations of ischemia (1 minute to 5 minutes), the pO_2 level rises sluggishly, often with a delay in any observable sign of pO_2 recovery. Overshoot of pO_2 values above the preischemic values are not seen.

Adenosine Receptors in the Central Nervous System

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Sponsor: *National Institutes of Health*

Purpose—The purpose of this study is to do a pre-clinical evaluation of both adenosine receptor and adenosine uptake site.

Results—We have described the complete anatomical distribution of the adenosine uptake site using (3H)dipyridamole autoradiography and shown by these binding experiments that there are multiple populations of brain adenosine uptake sites. Studies measuring adenosine uptake in synaptoneurosomes support the binding and autoradiography. More evidence has been gathered indicating that carbamazepine is acting as an adenosine antagonist.

Xanthine-induced seizures have been studied using the new A1-specific antagonist, XAC. Evidence was generated showing that XAC-induced seizures differ from those induced by caffeine in that they are not blocked by RO-15-1788, a benzodiazepine receptor blocker. We have also shown increased adenosine uptake sites in drug resistant human breast cancer cell cultures, suggesting that the adenosine uptake site may be involved in the phenomenon of multi-drug resistance.

Implications—Recent studies have focused on the role of adenosine agonists as protective agents during cerebral ischemia. The post-ischemic neuropathy is being characterized as it relates to adenosine, glutamate, and benzodiazepine status at both the binding and autoradiographic level. These studies will hopefully assess the potential utility of adenosine agonists in the treatment of stroke patients.

Basic and Clinical Studies of Neuronal and Glial Enolase

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Sponsor: *National Institutes of Health*

Purpose—The basic neurobiology and potential clinical utilization of neuron specific enolase (NSE) has been a long-standing interest in our laboratory.

Progress—During the past year, studies have begun to focus on the molecular biology of NSE in an effort to use the brain enolase isoenzyme system as a model to study neuron specific gene expression. We now have cDNA probes for both NSE and non-neuronal enolase (NNE) The probes have been characterized and *in situ* hybridization studies have been performed in the human brain. Our cDNA probe for NSE only labels neurons, whereas the probe for NNE preferentially labels glial cells. Studies performed using northern blots in both rat and guinea pig brain reveal that the mRNA for NSE is substantially larger than that for NNE. There is approximately a 75 percent homology within the coding region for human NNE and NSE (some 1,700 base pairs). The non-coding region is much larger for NSE and has very little homology to that of NNE, a fact we made use of to generate specific probes. Studies are in progress regarding the NNE to NSE switch that occurs during neural differentiation.

Future Plans—Studies are also in progress to determine the effect of cerebral ischemia on brain NSE levels in gerbil brain. In these studies, we will attempt to demonstrate that NSE levels can be used as an index of neural damage post ischemia. The effect of various protective agents such as adenosine receptor agonists will also be assessed. Clinical studies assessing NSE levels in both human CSF and serum consequent to stroke are also in progress. The goal here is to determine whether NSE levels are correlated with the degree of post-ischemic neurologic damage.

Observations on Cerebral Ischemia at Injury Threshold Levels

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Sponsor: *National Institutes of Health*

Purpose—Studies on mechanisms associated with survival of the neurons subjected to ischemia have important clinical implications, since elucidation of the nature of such mechanisms may ameliorate or prevent brain tissue damage following cerebral ischemia insults. In experimental research, the degree of ischemic injury which allows recovery of affected neurons is called "penumbra," that is, resembling a twilight zone around a solar eclipse.

Results—In our studies, we produced conditions of penumbra by subjecting cats to 20-minute occlusions of the middle cerebral artery (MCA), and studying various parameters of ischemic injury up to 2 weeks after the insult. Our studies demonstrated that although the animals showed significant and widespread changes up to 3 days after recirculation, there was either complete or partial recovery with regard to edema and neuronal damage, when animals were examined 2 weeks after MCA occlusion. Thus, our investigations resulted in establishing an experimental model where pathomechanisms associated with reversible ischemic damage could be analyzed and, potentially, manipulated.

Effect of Aminophylline on Post-Ischemic Edema and Brain Injury

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Sponsor: *National Institutes of Health*

Purpose—Effect of aminophylline on post-ischemic edema and brain injury was studied in cats subjected to the middle cerebral artery (MCA) occlusion for 1 hour.

Results—Administration of aminophylline 22.8 mg/kg infused for 15 minutes at the time of release of MCA occlusion resulted in suppression of reactive hyperemia and proved to have an unequivocal beneficial effect on development of post-ischemic edema and brain injury. The animals with aminophylline showed no breakdown of the blood-brain barrier to protein tracers and showed no significant edema in the ischemic regions, when sacrificed 3 hours after release of MCA occlusion. Also, cats with aminophylline treatment revealed significantly milder ischemic injury when studied histologically at 3- and 14-day periods after recirculation.

Implications—Our studies thus demonstrate a marked beneficial effect of aminophylline with a potential to be considered for treatment of patients in certain clinical conditions.

Microvascular Disturbances and Edema Formation After Repetitive Brain Ischemia

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Sponsor: *National Institutes of Health*

Purpose—The nature of the cumulative effect of three repeated 5-minute occlusions of the common carotid artery in gerbils, carried out during the period of post-ischemic hypoperfusion, was studied by visualization of cerebral microcirculation with intravenously injected Evans Blue (EB) tracer.

Progress/Results—The animals were sacrificed shortly after EB injection and the distribution of the tracer in the capillaries and larger cerebral blood vessels was studied in frozen sections under the fluorescence microscope. Repetitive ischemia caused progressively increasing brain edema and progressive reduction of the number of perfused capillaries. Immediately after each ischemic episode, transient recruitment of capillaries occurred, thus excluding no-reflow as a main pathogenic factor of microcirculatory disturbances. The pattern of microcirculation 6 and 24 hours after the last occlusion revealed a redistribution of circulating blood, characterized by a reduction in the number of EB-filled capillaries and, at the same time, noticeable dilatation of the larger vascular channels. The redistribution of microcirculatory flow was shown to be associated with the normal cerebral blood flow levels at that time.

Implications—Our studies suggest a closed interrelationship between post-ischemic microcirculatory hypoperfusion and the development of brain edema, the degree and extent of which progresses with the repetition of ischemic episodes when they are carried out during the periods of hypoperfusion.

Regulation of Hippocampal Dynorphin Levels and Synthesis After Ischemia

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Sponsor: *National Institutes of Health*

Purpose—Peptides derived from each of the endogenous opioid precursors were measured in gerbil brain regions after transient ischemia.

Progress/Results—Lasting depletion of dynorphin A immunoreactivity were observed only in the hippocampus. Levels of hippocampal dynorphin fell by 30 to 40 percent as early as one hour after recirculation, and remained at 50 percent of control for at least one week. In some experiments, peptide levels showed a transient recovery at 24 hours. Preliminary results suggest a similar reduction in hippocampal pro-dynorphin mRNA levels with a similar time course.

Implications—These results demonstrate at the neurochemical level a unique sensitivity of the dynorphin-containing dentate granule cell/mossy fiber pathway to transient ischemia. Although these cells remain histologically intact, the decrease in dynorphin precedes and continues during the delayed loss of hippocampal CA1 neurons characteristic of this model, and further defines the selective vulnerability of hippocampal circuitry following ischemia.

The mechanisms responsible for peptide depletion, and the functional roles of dynorphin peptides in the physiology and pathology of the hippocampus, remain to be elucidated.

Coordinate Changes in Brain Energy Metabolism and Protein Synthesis

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Sponsor: *National Institutes of Health*

Purpose—This long-term project investigating the integral relationship between protein synthesis and other aspects of brain metabolism has provided the initial studies on which two new projects are based, dealing with stress protein induction, and the depletion of hippocampal dynorphin after ischemia.

Progress—Research continues to focus on ischemia, with direct emphasis on the regulation of protein synthesis as such. Effects of repeated ischemic intervals on brain protein synthesis are being investigated, using the gerbil model available in the laboratory.

Results—The role of hyperthermia in the reduction of protein synthesis after amphetamine administration has been demonstrated in mice, and correlated with enhanced drug-induced brain glycogenolysis at higher body temperatures.

Future Plans/Implications—Other studies will evaluate the role of initiation factor phosphorylation in the characteristic lasting reduction of protein synthesis after ischemia. On a more applied level, it is considered that protein synthesis activity may be used as an index of ischemic stress in the preparation of tissue slices, providing a means for optimizing brain slices which may be applicable in a variety of physiological studies.

Stress Protein Induction in Gerbil Brain After Ischemia

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Sponsor: *National Institutes of Health*

Purpose—Since the initial demonstration of induction of the major mammalian stress (heat shock) protein, hsp70, after transient ischemia, efforts have been directed toward: 1) quantitating increased transcription of hsp70 and other stress-inducible mRNAs after ischemia; and, 2) immunocytochemical localization of hsp70 induction in gerbil brain.

Results—Induction of both hsp70 and ubiquitin mRNA sequences have now been demonstrated after ischemia using cDNA probes. Ubiquitin mRNA is only modestly induced (70 percent increase) and peaks at 6 hours recirculation. Hsp70 mRNA is more strongly induced (more than 2-fold) and peaks at 12 hours, coincident with the time of maximal hsp70 translation previously determined.

A striking temporal and anatomical pattern of hsp70 induction was demonstrated in post-ischemic brain using monoclonal antibodies considered specific for inducible forms of the hsp70 family. Control animals showed immunoreactivity which was restricted to ependymal cells lining the ventricles, and this remained unchanged after ischemia.

During 24 hours recirculation after 10 minutes ischemia, hsp70 immunoreactivity appeared in dentate granule cells, in neurons of habenula and striatum, and in a number of basal forebrain and cortical regions. At 48 hours, intense reactivity was evident in CA3 neurons of hippocampus. By 96 hours, immunoreactivity was restricted to some residual staining of CA3 with strong labeling of entorhinal and other cortical regions.

It is of interest that positive cells are found in hippocampus and other limbic structures, circuitry which may be the anatomical substrate for proposed excitotoxic mechanisms of neuronal loss after ischemia. Accumulation of hsp70 was apparent in CA3 and dentate granule cells which survive transient ischemia, but was greatly attenuated in CA1 neurons which do not.

Implications—This heterogeneity in hsp70 induction may reflect variations in post-ischemic metabolic stress, as well as in the response to stress of various cell populations.

Orthokinetic Orthoses: Clinical Efficacy Study in Analgesia of Post-CVA Chronic Pain

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Sponsor: *Orthokinetics Research Foundation*

Purpose—The purpose of this study was to investigate the clinical efficacy of orthokinetics treatment by application of orthokinetic orthoses (cuffs) to the upper extremities of patients with post-cerebrovascular accident (CVA) pain.

Progress—The two subjects studied had severe, disabling, chronic pain that was not mitigated by alternative treatments: range of motion, and strengthening exercises. The time span since onset was 4 months to 32 months. The orthokinesis analgesia treatments were applied single-blind to the patients, in single-subject time-series A1-C1-A2-C2-A3-B1-A4-B2 of sequential phases, comprising nontreatment (negative control) phases A1-A4; placebo treatment phase C1 (in which plain bandage cuffs were used instead of orthokinetic cuffs); sham treatment phase C2 (in which orthokinetic cuffs were applied in "reverse orientation," i.e., rotated 180 degrees relative to the correct cuff orientation in the orthokinetics treatment phase); and correct orthokinetics treatment phases B1, B2. All treatments were applied single-blind. The criterion measure for pain evaluation was the Present Pain Intensity (PPI) Index (1-5, no pain = 0) based on the McGill Pain Questionnaire. A neurophysiological rationale invokes neurotransmitters of a dorsal horn enkephalinergic interneuron mechanism of antinociception, modulated by stimuli from the orthokinetic orthoses to cutaneous non-nociceptors.

Results—1) The patient was a 63-year-old female with left hemiparesis due to CVA 4 months previously. She had left shoulder-hand-finger pain syndrome. In each phase of the single-subject time-series, the patient's left upper extremity was taken passively through all ranges of motion to pain tolerance (PROM, 3 min): phase A1—no application of any cuffs; phase C1—application of plain placebo cuffs; phase A2—as A1; sham treatment phase C2—application of orthokinetic cuffs in "reverse orientation"; phase A3—as A1; orthokinetics treatment phase B1—application of orthokinetic cuffs; phase A4—as A1; and orthokinetics replication phase B2—as B1. Pain was unmitigated in all control phases (negative controls A1-A4; positive controls C1 and C2) (PPI = 3). In contrast, pain intensity was markedly reduced in orthokinetics phases B1 (PPI = 1) and B2 (PPI = 0). The results supported *internal validity of orthokinesis analgesia.*

2) The patient was a 52-year-old male with left hemiparesis due to CVA 32 months previously with severe shoulder-hand-finger pain syndrome. The patient had undergone physical therapy since release from hospital, with reduction of left shoulder subluxation, but no pain mitigation. Orthokinetic cuffs were applied, using the same method, and single-subject time-series design as in 1. Pain was unmitigated (PPI = 3) in negative control phases A1, A2, and A3; in placebo phase C1, and in sham treatment phase C2. Pain was substantially mitigated in orthokinetics treatment phase B1 (PPI = 1), with little carry-over of analgesia in control phase A4 (PPI = 2), and complete analgesia with carry-over in orthokinetics replication phase B2 (PPI = 0). The outcomes supported *internal validity of orthokinesis analgesia*, consonant with the proposed neurophysiological theory.

Future Plans—Currently, plans for the project include exploration of clinical efficacy of orthokinesis analgesia in persons with traumatic brain injury, and with chronic pain secondary to athletic injuries of the upper and lower extremities. Projected plans include a long-term cooperative clinical trial on the generalizability (external validity) of the application of orthokinetic orthoses in disabling conditions with chronic pain, as well as a long-range basic research study plan concerned with testing of a proposed neurophysiological mechanism of orthokinesis analgesia.

Publications Resulting from This Research

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Microcomputer-Based Cognitive Rehabilitation of Higher Cognitive Deficits

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Sponsor: *Scottish Home and Health Department*

Purpose—The aim of this research was to evaluate whether microcomputer-based programs could result in the alleviation of certain cognitive deficits arising from stroke and head injury. The use of software for such purposes is widespread, but as yet no randomized group studies evaluating such programs have been carried out, and very few controlled single case studies have been carried out.

Progress—The first phase of this study consisted of approximately 20 single case studies evaluating existing and newly-developed software programs aimed at rehabilitating attentional disorders on the one hand, and unilateral visual neglect on the other.

This was carried out on a range of patients who had suffered stroke or head injury. Some promising findings emerged in *some* patients, but not in all. This provided justification to carry on with the second phase of the project, namely two randomized controlled trials of attentional training, and of unilateral neglect training.

The first randomized trial compared cognitive rehabilitation lasting approximately 16 hours aimed at teaching compensatory scanning and attentional skills in a group of 36 patients suffering from unilateral visual neglect, all of whom had suffered right hemisphere strokes, with the exception of two head injuries, and one excised meningioma. The control procedure was approximately 11 hours of recreational computing, namely quizzes, word games, and anagram puzzles.

Results—A wide range of neuropsychological tests were given before, at immediate follow-up, and at 6 months follow-up. No differences whatsoever emerged between groups, and most patients remained quite disabled by marked unilateral left visual neglect. There were no trends in favor of the treatment procedure.

The second trial consisted of a similar comparison of attentional training aimed at a group of patients, approximately half of whom were young head-injured patients, and the rest were suffering from cerebral infarcts. So far, only immediate follow-up results are available for this group, and though a significant trend in favor of attentional training was apparent on one measure of attentional functioning the Paced Auditory Serial Addition Test, this apparent improvement had no effects whatsoever on general cognitive, social, or other functioning.

The training procedures used were in general at least as sophisticated as software already in use widely in the United States and elsewhere, and in the case of several of the programs, was considerably in advance of currently used software, both in terms of software engineering variables, as well as in terms of the existence of a coherent training strategy and neuropsychological basis for the training procedures. In spite of this, there were no clinically significant effects of the training. This must throw some doubt on the validity of computer-based cognitive rehabilitation procedures for the types of disorder studied in this research.

Publications Resulting from This Research

Microcomputer-Based Cognitive Rehabilitation of Visual Neglect: Three Multiple Baseline Single-Case Studies. Robertson IH, Gray JM, McKenzie S, *Brain Injury* 2:151-163, 1988.

Remediation of Attentional Difficulties Following Brain Injury: Three Experimental Single Case Studies. Gray JM, Robertson IH, *Brain Injury* (in press).

XIV. Geriatrics

Electromyographic Incontinence Alert Device

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B376-DA)*

Purpose—The purpose of this proposal is to develop an electronic device that measures the decline in electromyographic activity of the pelvic floor muscles preceding an involuntary detrusor contraction and produces an alert to the patient of an impending bladder contraction associated with subsequent involuntary loss of urine. The early warning provided to the patient by the unit will be used as biofeedback to teach the patient to control continence in a cost-effective method with readily available maintenance therapy.

Urinary incontinence is one of the major social and economic problems affecting the elderly population in our country. Incontinence in the aged is the second major cause of admissions to long-term care facilities producing a total annual cost of more than eight billion dollars. Medical and surgical management of urinary incontinence in this group of patients has had limited success and a strong effort is being focused on behavioral therapy of incontinence at this time. Treatment modalities such as biofeedback have proved to be successful interventions but have the problem of the cost of administering therapy and providing maintenance therapy.

Urodynamic evaluation of bladder function in the aged incontinent patient shows most patients to have involuntary detrusor contractions associated with urinary incontinence. The onset of an involuntary detrusor contraction is preceded by a sharp fall in electromyographic activity of the pelvic floor muscles that occurs 6 to 8 seconds before the rise in detrusor pressure is detected. Using the principle that the fall in electromyographic (EMG) activity precedes the involuntary detrusor contraction, the purpose of this project is to design, build, and evaluate an electronic device that will detect the fall in EMG activity and alert the patient of an impending detrusor contraction. This early warning system will provide the patient with a training device that will assist in preventing urinary incontinence as well as teach the patient the skills required to control urinary continence. The device can be worn by the patient and will serve as a biofeedback training and reinforcement unit that is inexpensive to use and can provide maintenance therapy over a long period of time.

Progress—The first phase of prototype development has involved continuous measurement of changes in perianal electromyographic activity that are associated with involuntary voiding in elderly chronic care inpatients. A 4-channel telemetric unit is utilized to obtain electromyographic analog activity for subsequent digital analysis of changes in wave form that are associated with involuntary contractions of the bladder. Two telemetric channels have been used for electromyographic activity measurement, another has been used for detection of urinary incontinence, and the other channel has been used for measurement of the activity level of the patient. The battery operated telemetric transmitter has allowed an EMG signal without electrical interference that is sometimes associated with connections to power lines.

Future Plans/Implications—The wave form analysis of the sphincter EMG activity will be used to further modify an incontinence alert device in order to allow accurate recognition of an impending involuntary detrusor contraction and subsequent incontinence episode. Clinical evaluation of the device and further modifications of the prototype design are planned during the project.

Accelerometric Detection and Analysis of Falls in the Elderly: A Pilot Study

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Purpose--Falls present a serious health hazard to elderly and partially-disabled ambulatory persons. Examination of spontaneous falls, including patterns of movement that lead to loss of balance, could provide information valuable in preventing falls or minimizing resultant injury. Acceleration is a parameter that can be measured to study falls; the main purpose of this pilot project is to determine whether acceleration measurements are useful in detecting falls and determining their cause. Movements of male and female subjects belonging to one of three groups—young, fall-prone elderly, or "normal" (without a history of recurrent falls) elderly—will be observed in laboratory and natural settings. Data on head and trunk accelerations, measured by 3-axis accelerometers, will be processed by a portable recorder. The lightweight recorder and small, non-invasive accelerometers will allow for free-moving measurements and real-time data processing.

Psychiatric Rehabilitation in Nursing Homes

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E403-RA)*

Purpose—Nursing homes are now the largest single place of care for the mentally ill, yet nursing home staff have had little or no training in working with psychiatric patients. Existing studies show deterioration in the behavior of mental patients after nursing home placement, when compared with similar patients randomly assigned to VA nursing care units or continued psychiatric hospitalization. In the face of further financial constraints and an aging population of patients, it is likely that even more psychiatric patients will be sent to community nursing homes. Many of these patients have a potential for psychosocial and functional rehabilitation and, in others, behavioral deterioration could at least be forestalled. Training and consultation to staff in nursing homes offer the potential for improving psychiatric care. The objective of this research is to test the effects of training and a cost-effective method of consultation for psychiatric rehabilitation in nursing homes.

Progress—Nine nursing homes were randomly assigned to either a training program designed to increase staff knowledge and attitudes about caring for the mentally ill or to control conditions. Following the training, mental patients admitted to the homes are studied regarding behavioral outcomes at 6 and 12 months as well as whether treatment goals were attained. Half of the patients will be randomly assigned to have their treatment goals discussed with nursing home staff so the effects of individualized feedback to staff about patients can be evaluated. If this study shows that the training and feedback improve staff knowledge and attitudes as well as psychiatric patient outcomes, then the method would be a cost-effective one for upgrading psychiatric services in nursing homes.

Results/Future Plans—The training of staff in nursing homes randomized to training was completed in December 1987. There were significant positive changes in attitudes, knowledge, and skill of staff in trained, compared with control, homes. Intake of patients into the 9 nursing homes randomized to training, ongoing consultation, or control conditions was initiated in January 1988. To date, 101 patients have met the criteria of a psychiatric diagnosis and have been pretested on their behaviors and goals for treatment. The plan is to continue patient intake, pretesting, and 6- and 12-month follow-up testings initiated at appropriate times.

Motivational Devices for the Promotion of Aerobic Exercise in the Elderly

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E425-RA)*

Purpose—The objective of this 2-year project is to evaluate the influence of exercise enhancement devices on the attitude and perception of exertion of young, middle-aged, elderly, and wheelchair-confined subjects. The use of different age groups is intended to ascertain if preference in environmental conditions during solitary aerobic exercise is age-related.

After physical and psychological testing, each of the 180 subjects will be allowed to select one of three commercially-available, stationary exercise devices upon which to exercise. Each of the stationary exercise devices may be used under all three of the experimental exercise conditions. One of the exercise conditions has the subject interacting with the device in a game-like protocol, that is, a video display reflects the physiological and motor reactions of the exercising subject. The video display is designed to be fun, challenging, and to motivate the user to increase the duration and frequency of exercise sessions. Moreover, the game protocol is programmed to keep the user safely within the limit of their exercise prescription. The second exercise condition involves a non-interactive video display of exercise views in pleasant environments, that is, environmental scenery, as the camera is moved at a bicycling or running pace. The subject's heart rate will be superimposed on the video screen to provide information to the subject. The third exercise condition involves stationary exercise without the use of any motivational devices, simply an informational display of the subject's heart rate on the CRT screen, in order to allow him/her to stay within exercise prescription limits.

Progress—All exercise equipment has been procured and subject recruitment strategies are being developed. Pilot testing of the devices, equipment, and protocol began in November, 1988, and the experiment stage will start in March, 1989.

Spatial Orientation and Wayfinding in Elderly Persons

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E428-RA)*

Purpose—The purpose of this project is to provide a better understanding of the component processes of wayfinding, and to evaluate the impact of changes in wayfinding on the daily functioning of the older person. This will be particularly important following the person's relocation to a new environment.

Methodology—The procedure for this study is to compare individuals of three specific age groups in a residential setting. The comparison wayfinding efficiency includes the components of: 1) knowledge of the environment; 2) knowledge of one's location in relation to specific landmarks in the environment; and, 3) retrieval and usage of this information. Factors related to wayfinding competence in the elderly will also be studied, and include: 1) frequency and range of travel; 2) wandering behavior; and, 3) mood.

Progress—This study is presently in its initial stages. Tests in the areas of mood assessment, assessment of spatial orientation, wayfinding, layout knowledge and distance- and near-visual testing have been developed, and are currently being pilot-tested. In addition, work is being accomplished in the areas of equipment construction, development of data and record sheets, orientation routes in the VA and Wesley Woods Retirement Centers, and spatial mapping devices. Contact with the retirement centers has been made and subject selection and testing are under way.

Evaluation of Wandering Behavior in Elderly Persons and Interventions: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E926-PA)*

Purpose—The purpose of this project is to provide a better understanding of wandering behaviors in nursing home residents and to determine whether wandering activities can be altered by various types of feedback.

Progress—A pilot study was conducted at the VAMC-Atlanta nursing home in April-May, 1987 which impacted the design of further work. The behaviors of 5 male nursing home patients identified as wanderers (age range = 74 to 92) were videotaped whenever they traveled near the main exit from their floor of residence. Each time a subject was detected near the exit, during intervention periods, a computer-generated voice instructed him to return. The number of times the wanderer continued to exit or complied with the instruction was compared to pre-intervention rates (baseline). Three of the 5 subjects were ambulatory and accounted for 85 percent of the total number of observations. For 2 patients, unauthorized exits were virtually eliminated. The current project replicates this pilot research in a larger sample and attempts to precisely define wandering phenomena and related factors.

The current project is being conducted in two phases. Subjects are 30 older nursing home residents from a large metropolitan nursing home, 20 who have been identified as "wanderers or potential wanderers" by nursing staff, and 10 nonwandering patients as controls. All subjects have been evaluated with regard to background information, medications dispensed, and were administered a psychological test battery to assess their level of dementia and depression. In the first phase, which lasted 4 weeks, subjects' naturally-occurring behaviors were videotaped when they were detected in the vicinity of an exit door or elevator. A scoring system is being developed by the investigators from these video recordings. The scoring system will be applied to all videotaped observations by trained raters.

In the second phase, only wanderers' behaviors will be videotaped for an additional 4 weeks as a function of their location near major exits. However, at close range to an exit, they will be presented computer-generated verbal feedback instructing them, by name, to return to a safe area.

Data will be described with respect to wandering response patterns, demographic data, medication regimens, and psychological impairments. The impact of the intervention will be reflected in changes in the rates of wandering activity from Phase I to Phase II.

Preliminary Results—Initial assessment data has been collected and is now being analyzed. Over 9,000 Phase I events have been taped. These events are being analyzed in order to develop the coding system. Phase II intervention data are now being collected.

Future Plans/Implications—Based upon the results of this study, the investigators will evaluate a variety of feedback options and their effects on the wandering activities of elders with different characteristics. The long-term goal of this research program is to generate information which would allow the prescription of devices or treatments for wanderers who reside in institutions or in the community.

Publications Resulting from This Research

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Wandering Sequences and Behavioral Interventions in Older People. Martino-Saltzman D. *Proceedings of the ICAART Conference*, Montreal, 638-639, 1988.

Technology Applied to the Problem of Wandering Behavior in the Elderly. Coombs F, *Proceedings of the ICAART Conference*, Montreal, 640-641, 1988.

Assessment of Age-Related Changes in Visual Spatial Organization

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C426-RA)*

Purpose—This is a 3-year study of age-related changes in visual function and the perception of distance and depth. In the study, visual performance is being assessed on 200 normally-sighted individuals from two age groups, 20-35 and 55-70 years of age. The participants' performance on a battery of clinical and physiological tests of vision will be compared with their judgments of distance and depth in several psychophysical tests. These data will be used to determine the relationships among basic visual function, age, and perceptual judgments of distance and depth. A baseline evaluation will then exist upon which comparisons of other groups (e.g., older, low-vision observers) may be made.

Progress—A 20 × 30 foot room has been configured as a vision laboratory for this study. A subject testing booth and three alleyways have been designed and constructed. One alleyway permits the testing of dynamic accommodation and pupillometry, and the other two alleyways are used for static and dynamic spatial perceptual judgments. Programs have been written to control stepper motors which will drive accommodative targets for the infrared retinoscope under construction. Other programs have been written to assess the nonlinear responses of the observers' accommodation to targets moving nonpredictively in depth. Stimuli have been designed to assess distance and depth perception in frequently-encountered situations, such as viewing familiar objects, walking on stairs, and walking in areas of differing luminances and surface patterns. Stimuli for other depth situations (e.g., assessing closing velocity) are being designed.

The first year of this study is concerned with constructing the laboratory environment and stimuli. No observer data have been collected.

Implications—This study will establish normative data for future studies which will investigate the effects of age-related pathology upon visual distance and depth perception.

Pupillary Function in Elderly Individuals with Impaired Night Driving Vision

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E411-RA)*

Purpose—The goal of this research is to determine the cause of poor night driving vision in elderly individuals. Age-related alteration of pupillary function is a variable which may impact on the adaptive visual ability of the elderly in situations where light intensity changes rapidly, as when driving at night against oncoming traffic.

Many people over age 60 describe difficulty seeing when driving at night, to such an extent that they feel unsafe while driving. These people either continue to drive and pose a threat to their own safety and that of other drivers, or they restrict their driving to daylight hours and thus are limited in their mobility and ability to participate in social functions at dusk or at night. A significant proportion of the veteran population falls into this age category.

A solution to this problem is to identify the cause of impaired night driving vision by examining the physiology of vision as it relates to night driving. Because night driving involves rapid changes in light intensity (as in driving against oncoming traffic), and because alteration in pupil size is the physiologic means of regulating the amount of light entry into the eye, this study will establish whether changes in pupillary function are related to this problem. If this relationship exists, it may provide an impetus for better illumination of roads and highways to ensure the safety and improve the quality of life to the elderly. To date, 140 volunteers have been enlisted to participate in this study, as funding is made available for its implementation.

The tasks of this study are to quantify the prevalence of poor night driving vision and establish any relationship between this symptom and abnormal pupillary function.

Non-Auditory Factors Affecting Hearing Aid Use in Elderly Veterans: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #C952-PA)*

Purpose—This pilot project will examine non-auditory factors that influence successful use of hearing aids in elderly veterans. These factors include cognitive status, fine motor coordination, family support, and visual acuity. They are frequently mentioned in the literature when considering amplification for the hearing-impaired elderly. However, the influence of these different components has not been systematically evaluated in an effort to predict outcome with hearing aids.

The short-term goal of this study will be to review, isolate, and assess non-auditory factors that can be measured in a systematic way. A secondary goal would be to evaluate the utility of the Hearing Handicap Inventory for the Elderly (HHIE) with elderly hearing-impaired veterans. At the culmination of the pilot study, it is anticipated that a proposal will be submitted for a multi-year grant to study the non-auditory factors that have a significant relationship with successful hearing aid use in elderly veterans. Selected factors would be analyzed (multiple linear regression) to determine how each influences hearing aid use and how they interact with one another.

Further study might be aimed at evaluating whether those factors that prove to be predictors of limited success with hearing aid use can be improved or circumvented to increase the likelihood of success with amplification.

Progress—To date, 30 subjects ranging in age from 58-77 years (mean = 67.43) have received an initial evaluation. This included pure-tone thresholds, spondee thresholds, word discrimination tests, measures of most comfortable loudness/uncomfortable loudness (MCL/UCL), and tests of acoustic immittance. Additionally, the HHIE was administered in a face-to-face format. Measurement of the following non-auditory factors was also obtained: cognitive status (Short Portable Mental Status Quotient), visual acuity, social support, and fine-motor coordination.

Each of the 30 subjects has also received a hearing aid evaluation, including unaided and aided assessment of spondee threshold, word discrimination in quiet, and in a background of noise. Eight subjects have been fitted with hearing aids. None have yet been seen for follow-up and reevaluation.

Age-Related Changes in Sensory-Motor Performance

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Purpose—The goal of this research is to achieve an integrated understanding of the changes that occur in sensorimotor performance as healthy people grow older. We are measuring alterations in the processing of information in peripheral nerves, muscles, spinal cord, and supraspinal structures, as well as alterations in muscle strength and joint stiffness in healthy aging adults. These measures are being compared with changes in such functional tests as walking patterns (gait) and postural stability and steadiness (balance). We also intend to identify neurophysiological and biomechanical performance measures in subjects with central nervous system (CSN) damage which may explain an individual's gait pattern and measure of postural stability and steadiness. Parameters of sensorimotor performance from healthy aging subjects will be used as a "template" against which to compare elderly patients with neurologic disease. In this way, we hope to understand more about performance deficits that occur as part of the aging process, as opposed to those deficits which are characteristic of a neurologic disease state.

Progress—We are evaluating a population of normal healthy individuals up to 85 years of age, and a population of patients with such neurologic diseases as spinal cord injury, multiple sclerosis, stroke, cervical spondylosis, Parkinson's disease, and Alzheimer's disease. We are implementing measures which objectively evaluate segments of the neuromusculoskeletal system (myotatic reflexes, joint compliance, muscle strength, simple ankle joint voluntary movements, somatosensory evoked potentials) and methods which identify systemic functional integrity (standing balance and gait). Correlations are being made of the study variables for each test procedure to test hypotheses about changes in sensory-motor performance in older subjects. Special attention is being paid to variations in data from healthy aging subjects who report a history of falling, or who have a sense of "unsteadiness."

To date we have collected data from 44 normal young adult volunteer (ages 18-40 years) to establish statistical norms as a basis of comparison for the study of healthy aging (ages 45-85 years) and neurologically-impaired subjects. Sensory-motor performance tests have been performed on 53 men and women whose ages range from 52 to 85 years.

Our entire database of integrated assessment measures currently includes serial and longitudinal data on 300 subjects, including normal children (11), prosthetic patients (1), and patients with neurologic diseases such as spinal cord injury (21), cervical spondylotic myelopathy (77), multiple sclerosis (9), stroke (2), developmental delay (15), Alzheimer's disease (4), and other pyramidal and extrapyramidal diseases.

Preliminary Results—Most of our healthy aging volunteers (45-84 years old) participate in some type of routine exercise, including walking from 2 to 5 miles daily. Despite this level of participation in a "fitness" program, a number of these subjects are unable to perform tandem walking, have deficits in deep tendon reflexes by neurologic exam, have some frontal release signs, diminished myotatic reflexes, and alterations in the later components of the somatosensory evoked potential. Correlations among these aberrant measures with joint stiffness, reaction times, postural stability and steadiness, and other kinematic and kinetic measures of gait are currently being performed.

Our tests of the healthy aging population have also identified alterations in electrophysiologic and functional measures which are consistent with neurologic disease (usually early cervical spondylotic myelopathy) in four subjects.

Future Plans—We are beginning to define the broad spectrum of changes in function, as well as electrophysiologic and biomechanical measures, which occur as part of the aging process in healthy men and women. We intend to continue testing healthy aging subjects so that all age groups are more equally represented by both men and women. We are also beginning to identify trends in deficits as part of the aging process, and correlated aberrant measures in individual subjects and in different age groups. In this way, we are developing the "template" of sensory-motor performance in healthy aging, against which we can compare our subjects with neurologic disease.

Dynamic Postural Sway Measurement in Elderly Fallers

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Sponsor: *VA Rehabilitation R & D Unit, VA Medical Center (Atlanta) Core Funds*

Purpose—Excessive postural sway or upper body precession from the vertical axis has been directly and indirectly related to incidents of falling. Sway, quantified as postural instability, has typically been measured statically. How this relates to sway during ambulation is unknown. This study addresses the use of a triaxial accelerometer-based system to determine deviations from the vertical in the mediolateral and antero-posterior planes of subjects during ambulation. The detection and quantification of dynamic sway can be used to predict the potential for falling, based on physiological stability and the potential contribution of environmental cues. Quantified measures of dynamic postural sway can be used to develop characteristic profiles of baseline and comparative floor surface data. This, in turn, could provide insight into the effect of floor surfacing on postural stability.

Progress—A simple yet adaptive system was developed providing for the dynamic analysis of postural sway. This system consists of four primary components: a triaxial accelerometer, its associated signal amplifiers and power supply, and an IBM PC/XT microcomputer. The former two are worn by the subject in a belt/backpack combination, while the latter two are located on a laboratory benchtop.

The accelerometer is attached to a belt worn around the waist and located posteriorly at the upper portion of the sacrum or lower lumbar region, thus in close external proximity to the subject's center of gravity. (The center of gravity is the most stable point of any body in motion.) Therefore, eccentricities/motions of this locale are most indicative of total body movement. The triaxial accelerometer uses inertial loading of small cantilever beams equipped with strain gauges. Each axis contains bridge circuitry sensitive to accelerations or motions experienced by the unit. This transducer is especially stable at the low accelerations experienced during human motion.

Through the use of sampling circuitry, it is possible to obtain discrete values from the continuous accelerometer data. These data may then be treated in various ways by programming the personal computer. Filtering of data is often necessary to remove signal noise. Digital filtering removes noise from discrete data signals by creating a new signal which consists of a combination of data values from both the original signal and the filtered signal. A simple algebraic relationship between the two signals produces the new signal which may be obtained through computer programming. Fourier analysis of the signals permits identification of harmonic frequencies in repetitive motions.

Preliminary Results—Testing of the system consisted of a 2-phase protocol. The first phase focused on equipment validation in the laboratory, and included testing of the hardware and several data-capture software routines. The second phase was conducted to check intraindividual testing reliability of the measurement system. This phase involved the use of in-house subjects. Instructed to ambulate in their normal mode without gross exaggeration of movement, the subjects were allowed several practice runs before actual data capture occurred. Each subject was tested twice a day, at the same time each day, over a 3-day span. The resulting analysis indicated a fairly good intraindividual system response.

Future Plans/Implications—The system will be further validated through more extensive data capture, data analysis, and software refinement. Additional tests will be conducted examining the effects of flooring surface on postural sway.

Publications Resulting from This Research

Prototype Development of a System Providing for the Initial Assessment of the Dynamics/Kinematics of Bipedal Motion. Farris D, *Proceedings of the 10th Annual RESNA Conference,* San Jose, CA, 7:726-728, 1987.

Dynamic Postural Sway Measurements in Elderly Fallers. Farris D, et al., *Proceedings of the ICAART Conference,* Montreal, 642-43, 1988.

Repetitive Behaviors Exhibited by Alzheimer's Patients

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Sponsor: *VA Medical Center, Salem, VA*

Purpose—Research this past year has involved the development of a behavioral index scale to document the behaviors of dementia patients. When we initiated the pilot project on "Environmental Influences on Patients with Alzheimer's Disease" several years ago, it became apparent that one weakness of the project was the lack of a reliable instrument for identification of behaviors of Alzheimer's patients. We decided to develop such a tool, as well as document the behaviors which occurred most frequently, and were representative of patients with dementing illness. This second phase study was initiated with the purpose of identifying and documenting data on the naturally-occurring behaviors of patients with Alzheimer's disease and other dementias.

Progress—An index scale of behaviors was developed to assist nursing staff in assessing and systematically documenting behaviors on confused institutionalized patients, for the purpose of planning effective management strategies, health interventions and discharge planning.

The nursing staff at our Medical Center felt that a valid checklist for documenting specific behaviors related to Alzheimer's disease and other dementias was needed to facilitate not only the documentation process, but treatment planning and interventions for frequently-occurring behaviors that could have a negative impact on the confused individual. Staff was also interested in assisting families and health care providers in patient care duties prior to and post-hospitalization for patients affected by the challenging diseases of the dementia type.

Using the Haycox Behavioral Index (1984) as a reference, we developed a behavioral index to be utilized when documenting behaviors of dementia patients. Extensive work and numerous observations were made prior to compiling the suggested list of behaviors. First, staff at two Medical Centers working with dementia patients were asked to list behaviors that they had observed most frequently in their patients. Second, the literature was reviewed to determine the behaviors previously documented on patients in this group. Third, behavioral observations were made of patients in their natural clinical setting. A final list was then compiled and behaviors grouped into categories as follows: vocal, interactive, non-personal, escape, and self-directed. Within each category, specific criterion behaviors were listed. We plan to utilize this scale to document behaviors when other environmental stimuli are used in the pending proposal.

Results—We have made observations of patients' behaviors using our index. Data analysis revealed the behaviors of patients diagnosed as having Alzheimer's disease and similar types of dementia are clearly repetitive, and more frequent in both verbal and self-directed activities. The patients who were more physically and cognitively impaired, based on the Haycox Rating Scale score, displayed a higher incidence of all observed behaviors.

Future Plans/Implications—The results of these observations could be used to assist care providers in planning nursing strategies that are useful in dealing with Alzheimer's patients, as well as patients diagnosed as having other types of dementia. Further, one potentially useful technique would be environmental manipulations to assist with patient care interventions. Also, time of day may well be a factor in determining when the patient is amenable to various therapeutic interventions.

Nurses and other health care providers are encouraged to work collaboratively to pursue the investigative process relative to behavior and the effects of environmental stimuli on behaviors. We recommend sharing findings and behavioral concerns that arise in the naturalistic clinic setting, to aid in the pursuit of rehabilitation and excellence in geriatrics. Future plans are to continue investigative endeavors in the area of identification for those routine environmental conditions which decrease repetitive behaviors, especially in the areas of light and sound. Additionally, engineers who design facilities to provide care for confused, older adults, could consider environmental stimuli that affect or alter certain criterion behaviors identified in our checklist.

Fighting Blindness with Certain Forms of Eye Pathology

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this study is to determine whether an objective measuring method can help fight the effects of blindness in certain forms of eye pathology (cataract and other forms of medium cloudiness). With these complaints, the blindness is caused by diffused light. By applying a new technique, a better idea can be obtained about the factors determining the extent of the diffused light, and, it is hoped that it will be possible to specify conditions with which the consequences of the defect can be limited as much as possible. Should the research be successful, a machine will be constructed that is suitable for use in the ophthalmic clinic/practice. The diffused light which occurs with various defects, will first have to be defined.

Progress—From the various data collected, it may be concluded that the diffused light function of most examined patients was considerably increased. A tenfold increase of the usual level is no exception. This contributes greatly toward determining the visual handicap, which cannot be measured in any other way. These results are the basis for the proposition that it would be sensible to have an instrument available in the clinic for the routine checking of diffused light.

This project was undertaken with the cooperation of the University of Amsterdam, Ophthalmic Department, and the Academic Hospital with the University of Amsterdam (AZUA). In the course of the project, the following have also taken part: State University Groningen, Ophthalmic Department; Erasmus University Rotterdam, Ophthalmic Department; and, Delft University of Technology, Faculty of Industrial Design.

Aging with a Disability: The Late Effects of Polio

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Sponsor: *National Institutes of Health, National Institute on Aging*

Purpose—The purpose of the research phase of the postdoctoral fellowship is to examine the social role modifications, value orientation shifts, and coping strategies developed by a group of middle-aged, motor-disabled individuals who are learning to adapt to the new health problems associated with the late effects of polio. Approximately one-third of the 500,000 American polio survivors report new disabling symptoms 25 to 30 years after infection by the polio virus. The symptoms of the late effects of polio or "post-polio sequelae" include: muscle weakness, muscle and joint pain, severe fatigue after moderate activity, sleep and breathing difficulties. The aim of the investigation is to identify successful and unsuccessful health maintenance strategies that contribute to a long-term disabled person's ability to continue to work and participate in household and leisure activities.

Subjects have been selected from a group of out-patients at the National Rehabilitation Hospital's Post-Polio Clinic, directed by Lauro Halstead, MD. Twenty-five individuals will be interviewed at length—in the clinic, at home, during lunch hours at the workplace, and during a leisure-time activity. Six hours of interviews per subject will be tape-recorded, transcribed, and analyzed in order to achieve an in-depth view of the social consequences of long-term motor disability.

The purpose of the training phase of the fellowship is to allow the investigator the opportunity to combine qualitative and quantitative methods in order to produce: 1) a broad portrait of the social strategies used by a group of polio survivors to adapt to the late effects of polio; and, 2) a measurement of rehabilitation outcomes one year after patient evaluation in the Post-Polio Clinic. In collaboration with Dr. Gerben DeJong (Director of Research), Dr. Lauro Halstead (Director of Post-Polio Clinic) and Ms. Deborah Wilkerson (Director of Program Evaluation), the investigator will develop and implement a pilot out-patient evaluation system that will measure the effectiveness of clinic treatment recommendations before and one year following clinic evaluation, including standardized measurements of functional status as well as recording shifts in social role and value orientation.

Progress—The research and training fellowship began on July 1, 1988, and to date the investigator has developed an open-ended questionnaire protocol, initiated contacts with several subjects, and has been integrated into the Post-Polio Clinic rehabilitation team.

Future Plans/Implications—Most clinicians agree that the new health problems associated with the late effects of polio can be minimized or even reversed by energy conservation techniques, reduction of activity levels, and the use of additional adaptive devices (such as wheelchairs, braces, or canes on a full- or part-time basis). Social and environmental modifications in the home and workplace are often recommended for the reduction of pain, tiredness and stress. The human costs and benefits of changes in values, attitudes and behaviors arising from the late effects of polio will be documented. The research has significant implications for other cohorts of the aging disabled population, such as the spinal cord injured.

The Use of Technology to Promote Rehabilitation of Older Persons: Reducing Barriers to Independence

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Disabilities often make it difficult for the older person to function maximally at home; such persons are also at increased risk of injury through accidents. The effective incorporation and use of environmental features are central to the safety and rehabilitation of the older person, i.e., to maintain independence, prevent further disability, reduce family worry, and prevent institutionalization. Although technology has been widely used to solve problems of rehabilitation, this has not been particularly true in geriatric rehabilitation.

This project's ultimate goal is to develop a sub-center on technology within the Rehabilitation Research and Training Center on Aging. Focusing on safety problems in the older disabled persons' homes, a set of critical problems will be identified.

Existing commercial products designed to solve such problems will be tested in the home and/or laboratory setting and modifications and developments of products will be conducted to fill identified problem-technology gaps. These phases of the project will utilize data from groups of professionals working with older disabled persons as well as older disabled persons themselves.

Dissemination activities will be an important component in later phases of this project. The dissemination activities will include production of a home safety resource notebook, preparation of articles for publication, a central call-in telephone resource service, the development of product utilization workshops, and the presentation of information at conferences concerned with geriatrics, rehabilitation, or human factors.

Progress—The project has just begun. Initial efforts are focusing on compiling a comprehensive literature base as well as establishing a method by which the products/technologies to be studied can be located and organized. Criteria are also being developed by which groups of professionals and older persons will be selected for participation in the project. Finally, pilot interview forms on safety and home environments are being assembled.

Assessment of Mobility Impairments in Older Persons

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Purpose—This study had three distinct goals: 1) to help establish normative data on the prevalence and degree of mobility impairment among older persons; 2) to evaluate the clinical validity of community ambulation criteria established by Lerner and Vargas (1983); and, 3) to examine the roles of various biological, psychological, and social problems in determining community ambulation status.

Progress—One hundred and sixty-one community dwelling elderly subjects who were seen in the Geriatric Assessment Clinic at Rancho Los Amigos Medical Center were subjects in this study. The subject group had a mean age of 75.5 years. Sixty-six percent of these subjects were female, 66 percent Caucasian.

The clinical assessment included evaluations from medicine, pharmacy, psychology, physical and occupational therapy, audiology, dentistry, podiatry, and neurology and psychiatry (the latter two if indicated). In addition to this, for purposes of this study, subjects were also evaluated on five community ambulation criteria proposed by Lerner and Vargas. This involved: 1) ambulation of 332 meters on a level surface; 2) ambulation at greater than 79 m/min; and, 3) negotiation of a ramp, curb, and three steps. Each subject was evaluated as independent or dependent on these tasks. Subjects were also questioned regarding their frequency of participation in 15 community and seven home-based leisure activities, and their level of independence in activities of daily living (ADL) and instrumental ADLs (IADL). Other data collected included the number of medical, family, and social problems uncovered during the geriatric assessment, the number of current medications, and measures of depression and life satisfaction.

Results—Initial findings indicate that the relationship between community ambulation and the number of community leisure activities participated in is low. While moderately correlated, the relationship between mobility impairments and community IADLs is also clinically insignificant. There was a high level of disability in this group. Specifically, only 6.2 percent of the subjects met all five criteria items and only 52.8 percent met all the criteria except for the velocity. Yet there was not a clear difference in levels of activities between the groups that could meet the criteria compared to those who could not. This suggests that factors other than physical disability may effect an elderly person's participation in community activities. Factors such as depression, income, or social supports may be more related to actual function for elderly people. Further analyses are being done to address these issues.

We are also investigating the relationships between the ability to perform ADLs and IADLs and the levels of mobility impairment and community activity.

Future Plans/Implications—It is important to identify those factors impairing or inhibiting an older person's ability to function in the community. As our analyses bring this information to light, we will disseminate it to aging and rehabilitation professionals.

Attitudes Of and Toward Older Persons with a Disability: Their Measurement and Their Role in Rehabilitation

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Purpose—This study is a 5-year project to develop psychometrically sound scales that measure attitudes of and toward older persons with a disability. The project will also investigate the impact that attitudes of the patient, his/her family, and the primary care doctor have on the rehabilitation process and outcome of older disabled patients.

Successful rehabilitation outcomes for older disabled persons are not always due to the person's efforts and capabilities alone. The patient's family and primary care doctor both play a large part in determining the adequacy of the older persons adjustment, level of functioning, health status, and life satisfaction (Brody & Ruff, 1986). In addition, the attitudes of the older disabled patient, his/her family, and the primary care doctor toward the disabled older patient may operate strongly as either barriers or facilitators in the rehabilitative progress (Altman, 1981; Kemp, 1986). Positive attitudes may facilitate quick and lasting successful rehabilitation. Negative attitudes may lead to decreased rehabilitation motivation, poorer health care, and second class treatment of the patient (Gilmore, 1975; Treischmann, 1987).

To date, no instruments exist that specifically measure attitudes toward the elderly with disabilities. This study is expected to produce two such scales: one for disabled elderly and one about disabled elderly. These scales will fill a void that exists in the rehabilitation research and allow for further investigation and understanding of the attitude-rehabilitation relationship and outcome.

Following development of the two scales, the primary goal will be to investigate the rehabilitation outcomes in relation to attitude patterns among the family, the doctor, and the patient. These findings will highlight which attitudes interfere with which rehabilitation outcomes, and disseminate information on how to reduce these barriers.

Progress—This project has just begun. A resource file of prior measures in disability attitudes and measures of general attitudes toward the elderly has been created, and an extensive item pool is being developed for the two attitude scales.

Each attitude scale will include 45 items divided into three subscales of affective, belief, and behavior-intention attitudes. Test-retest and split-half reliability statistics will be done and standardization norms will be acquired from a national sample. Validation studies will be performed on 4 indices of attitudes, i.e., life satisfaction, satisfaction with social activities, daily living activities, and professional nominations of both older disabled with positive attitudes, and families with positive attitudes.

After the measures are completed, the role of family, patient, and physician attitudes will be investigated on a number of rehabilitation outcomes, including social participation, life satisfaction, living arrangements, health status, patient and family mood, and family interaction.

Assessment of the Prevalence, Psychosocial Correlates and Risk Factors of Urinary Incontinence Among Disabled Older Persons

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Purpose—Urinary incontinence is a common, distressing, and potentially disabling condition in the elderly. Estimates of incontinence for the elderly vary from 5 to 20 percent for community dwellers, and from 50 to 60 percent for institutionalized elderly. This study's purpose is to determine the prevalence of urinary incontinence, the relationships between incontinence and existing medical diagnosis and physical conditions, and the relationship between urinary incontinence and psychosocial well-being of elderly disabled adults.

Progress—A self-report questionnaire was developed for the project. In addition to subtypes, symptoms, and frequency of urinary incontinence, the questionnaire assesses a person's mood, coping style, and social interactions. One hundred and fifty-five community-dwelling elderly (mean age = 76, 68 percent female, 69 percent Caucasian) were given the questionnaire. The sample comprised persons who came to the Rancho Gerontology Service for a comprehensive geriatric assessment because of physical, psychological, or social problems that were jeopardizing their ability to live in the community.

Results—Subjects were classified as incontinent if they responded positively to any of the following questions: 1) Do you ever pass your urine when you don't want to? 2) Do you ever have trouble getting to the toilet on time? 3) Do you have accidents getting your clothing wet? or, 4) Do you have accidents getting your bedding wet? According to this criterion, 100 (65 percent) subjects were identified as incontinent; 55 were classified as continent. However, only 47 (30.5 percent) of the 155 subjects were identified as incontinent by clinical geriatric assessment.

Other preliminary analyses compared the level of depression between subjects who were identified as incontinent and those who were not. The incontinent group had a significantly higher mean on the Yesavage Depression Scale ($t = 4.9$, $p < 0.001$). Differences in coping methods were also compared. There were no significant differences between incontinent and continent groups.

Future Plans/Implications—Continuing efforts on the project are focusing on more in-depth data analyses. Using factor analysis, an attempt is being made to extract those self-report items which are most effective at identifying incontinence as well as behaviors related to incontinence. Analyses are also looking at accurate identification of incontinence sub-types, e.g., stress, urge, overflow, etc. A third task is concentrating on understanding changes in function and/or social interaction which may be related to being incontinent. Finally, the above-mentioned discrepancy between prevalence of incontinence obtained by the self-report questionnaire and the clinical assessment merits further exploration.

Late Life Effects of Early Life Disability: Physical, Psychological, and Socioeconomic Characteristics Comparisons with Age-Matched Controls

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Purpose—Increased attention has recently been placed on the late life problems affecting people with an early life onset of disability. Most persons with disability are living to late life, but many are experiencing the onset of new medical and functional problems. Two of the largest such groups are people with post-polio and spinal cord injury (SCI). Post-polio individuals are experiencing primarily fatigue, weakness, pain, and loss of strength. The SCI population is experiencing multiple medical problems. To date, no studies have been conducted which compare disabled persons to appropriate age-matched control subjects, and relatively little attention has been focused on the long-term psychosocial consequences of an early life disability. This study will correct those shortcomings by focusing on a variety of medical, psychological, and social variables among persons with disability, late onset controls, and nondisabled controls. It will also test a number of hypotheses regarding the nature of these problems. Further, this study will gather data on unmet support system needs.

Progress—This is a 5-year study that was initiated in April, 1988. We are at present evaluating instruments to be used for data collection and making arrangements for subjects through the post-polio and SCI clinics at Rancho Los Amigos Medical Center.

The Effect of Age and Visual Loss on Independent Outdoor Mobility

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project has two parts. The purpose of Part I is to assess the effect of advancing age and severe visual loss on travel capabilities and habits of individuals in their home community. In addition, measures of satisfaction with travel and perceived needs in mobility are being obtained. This study is important because little is known about travel patterns of visually-impaired persons in their home communities, and the combined effect of aging and visual loss have not been studied at all. Part I was completed in the Fall of 1988. During Part I, researchers have conducted in-depth interviews about mobility with approximately 80 individuals, including visually-impaired persons 60 years of age or older and a group of younger individuals with similar degrees of visual loss. Older persons who have normal sight have also been interviewed. Ultimately there will be approximately 120 interviews completed.

Preliminary Results—Reported frequency of independent travel and satisfaction with travel have been assessed in light of such factors as physical and mental health, family support, economic status, and the type of environment where the participant lives and travels. Preliminary results indicate that the duration of blindness and fear of crime are related to independent travel frequency among older blind and visually-impaired persons, and together account for approximately 30 percent of the variance in travel. Further analyses will be conducted to determine effects of age and degree of visual loss on various measures of travel.

Future Plans—In Part II, to begin in early 1989, participants will walk routes "seeded" with a variety of travel situations (e.g., stairs, curbs, obstacles). Videotapes will be made of the walks, and tapes will be scored as to the number of contacts with objects and other behaviors. Lighting and color contrast will be varied along the route. The study will allow researchers to determine the effect of age and degree of vision loss on one's ability to safely negotiate common travel situations.

Motor Control of the Aged

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Sponsors: *National Institutes of Health, National Institute on Aging*

Purpose—Changes in the neuromuscular apparatus accompanying the aging process are well known. These include decrease in nerve conduction velocity, shift toward slower muscle contracticle characteristics, and decrease in the total number of ventral root axons. The average size of the recorded motor unit action potentials increases, due to an increase in the size of each motor unit, as muscle fibers which lose their innervation are reinnervated by neighboring axon twigs. The increased motor unit size and the decline in neuromuscular transmission efficiency result in an increase in the duration of the motor unit action potential, as well as increased neuromuscular jitter. There are few studies regarding the firing rates of aged motor units or how the normal aging process results in changes in motor unit interactions. In this study, experiments utilizing the decomposition procedure to study motor unit firing behavior in older adults were performed.

Progress—Motor unit firing patterns were studied in the first dorsal interosseus (FDI) and the tibialis anterior (TA) muscles in 10 aged (mean = 75 years) individuals with no known neuromuscular disorders. Each individual performed a series of slow, isometric muscle contractions at 40-60 percent of maximal voluntary contraction (MVC). Each contraction lasted approximately 20 seconds. Rates of tension development did not exceed 10 percent MVCs.

Results—Motor unit action potentials recorded from older individuals tend to be longer in duration, greater in amplitude, and more polyphasic. They also tend to display more neuromuscular jitter than those recorded from younger subjects. In general, peak firing rates were greater for motor units from the FDI than for motor units in the TA, as is seen in younger adults. Also, in most cases, an orderly manner of recruitment-deactivation, similar to that observed in the younger population, was found. There were some instances, however, in which an aberrant mode of recruitment-deactivation was observed. These instances usually consisted of abnormal firing patterns of late decruiting high-threshold motor units. Thus, it seems that while some characteristics of motor unit discharge are similar to those observed in younger subjects, there appears to be some disruption in motor unit behavior which accompanies the aging process.

Phosphate and Calcium Homeostasis: Pathophysiology of Osteopenia in Aging

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Sponsor: *National Institutes of Health*

Purpose—This report lists studies on the regulation of mineral metabolism and the pathophysiology of osteopenia in aging. These findings summarize investigations on: 1) The loss with age of bone mineral from rat femurs, measured by single photon absorptiometry. 2) Bone status of the aging female rat. 3) Mineral homeostasis and skeletal histology in the aged female rat. 4) Characterization of the human osteosarcoma cell line (CRL-1427) as a model osteoblast-like human bone cell. 5) Regulation of bone resorption by a phenylalkylamine-sensitive calcium channel. 6) Biochemical mechanism of the age-associated decrease in vitamin D-sensitive intestinal calcium absorption. 7) Desensitization to PTH in renal cells from aged rats is associated with a decrease in PTH receptor binding sites. 8) Desensitization to PTH in renal cells from aged rats can be reversed by parathyroidectomy of the senescent animal. 9) Preparation of cDNAs of Gs, Gi, Go, and actin. 10) Pertussis toxin blocks the action of alpha 2-adrenergie hormones in blunting the response of renal cells to PTH. 11) PTH regulation of cytosolic Ca^{2+} in proximal tubules. 12) The PHT-induced increase in cytosolic Ca^{2+} is desensitized by PTH. 13) The PTH-induced increase in cAMP in OK cells is desensitized by PTH. 14) The concentration of ionized Ca in serum is unaltered in the aged male rat. 15) Regulation of PTH-independent phosphate uptake in cultured renal cells (OK cells) by calcium. 16) PTH enhances 25(OH) vit. D3 1-hydroxylase activity in renal cells.

Investigations of Bone Mineral Density and Bone Loss

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Sponsor: *National Institutes of Health*

Purpose—Bone loss together with osteoarthritis is one of the two principal aged-related changes of the human skeleton. Even though these changes are considered universal phenomena inherent to aging, they may result in incapacitating ailments. Advanced bone loss may result in osteoporosis and frequent bone fractures.

At some time during the fourth decade of life, the human skeleton begins to lose bone. That is, bone mass decreases in relation to bone volume. In tabular bones, bone is resorbed from the endosteal surface. Because of the thinning of the cortical bone shell, bones lose their mechanical integrity and fracture more readily. The trabecular bone mass of the vertebral column also decreases with age. The vertebral plates decrease in density, lose resistance to vertical compression stress, and are more vulnerable to vertebral collapse. Vertebral compression fractures and fractures of the femoral neck are the most serious consequences of bone loss.

The following skeletal sites are involved in the present study: hand-wrist, ulna and radius, vertebral column, and the proximal femur (trochanter, neck, and Wards triangle). This project deals with the epidemiological, genetic, longitudinal, and biochemical aspects of bone loss among participants from Baltimore, and patients afflicted with Amyotrophic Lateral Sclerosis/Parkinsonism Dementia Complex of Guam. Also, our goal is to ascertain bone mineral differences between long-distance runners and relatively inactive normal controls, and study bone mineral density and the effect of muscular activity on bone in rats and other animals.

Osteoarthritis and Aging

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Sponsor: *National Institutes of Health*

Purpose—The most common rheumatic disease of the elderly is osteoarthritis. Forty million Americans are estimated to have radiological evidence of osteoarthritis; the majority are asymptomatic. Progressive increases in both numbers of persons involved and extent of osteoarthritic changes are known to occur with aging. However, it is not clear whether the rate of progression is the same in young, middle-aged, and older persons. Similarly, the rate of development of osteoarthritis is not well-defined. A controversy also exists regarding exactly where on the established scale of measurement for radiographic changes (0 to 4+, with 2+ considered to be definite disease) osteoarthritis actually begins. Cross-sectional studies provide valuable prevalence or correlative data and are important in determining the relationship between radiographic disease, symptoms, treatment, and functional status. Longitudinal studies provide the insight into the natural history and long progression of aging and disease states.

This project is both a longitudinal study designed to determine the progression of osteoarthritis by evaluation of radiographic changes on hand X-Rays, and a correlative study to examine the interrelationship of symptoms, physical exams, and X-Rays in several joints.

Development of Home Health Care Car "Danlan"

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Sponsors: *Nissan Motor Co., Ltd.; Nihon Kohden Co., Ltd.; Nihon Telegraph and Telephone Co.*

Purpose—The number of aged persons increases every year, and many of them need some assistance or medical care in their daily lives. Considering these circumstances, we have developed the home health care car, "Danlan," by which an aged or infirm person can travel and be taken care of, if necessary. Four persons can ride in this wagon-car: a person in an electrically-powered wheelchair, two assistants taking care of that person, and a driver. The person in the powered wheelchair can ride in the car easily by the use of the power-lifter situated at the rear of car. The wheelchair is fixed to the car chassis, and by changing the seat position and widening the arm-rests, can be used as a bed as well as a seat. As the wheelchair is situated in the center of the wagon, the occupant can enjoy the scenery during the ride. This car makes it easier to go to a clinic for consultation or to go on an excursion. When the wheelchair occupant complains of abnormal symptoms, the attendant can call a doctor by using the car phone, and also transmit an ECG to take the necessary disposition. In this way, any medical emergencies can be dealt with as soon as possible.

Progress—"Danlan" has an electrically-powered wheelchair with a full reclining seat, thereby making daily life more comfortable for the aged or disabled person. The car is equipped with a transportable lavatory and medical equipment such as a sphygmomanometer, an electrocardiograph, and an oxygen inhaler. Equipment for acute medicine is always on board. Artificial dialysis equipment can be added for those with renal failure problems. TV and video sets are used for instruction on the use of the on-board equipment, as well as for its original use.

Preliminary Results—The transmission of electrocardiograms (ECGs) through the car telephone was tested. Since an ECG transmission is done in the form of a digital signal after A/D conversion and data compression, the distortion and noises due to transmission are virtually negligible. Thus, the doctor could easily decode the received ECG. Electrocardiograms of 3 to 12 channels can be transmitted simultaneously. The transmission test was repeated when the moving car was passing through a tunnel, and neither distortion nor noises were proved.

Future Plans—After all the ECG transmission tests have been completed, artificial dialysis tests will be scheduled to treat the chronic renal failure patient in this car. Total tests will follow.

Consequences of Discussing Do Not Resuscitate (DNR) Decisions with Elderly Patients: A Test of Physician Assumptions and Patient Reactions

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Sponsor: *None Listed*

Purpose—This is a 1-year project to investigate elderly patient reactions to a patient-physician discussion on whether or not they would want CPR or nonresuscitation following a severe cardiopulmonary arrest while hospitalized.

Some elderly hospitalized patients may prefer nonresuscitation following a cardiac arrest when the possibilities for healthy survival are slim. However, many physicians are reluctant to discuss the pros and cons of such a decision with their patients due to physician assumptions of negative and fearful reactions from the patients (Angell, 1984). As a consequence, many physicians have made life-or-death medical decisions for their patients, many of which have later been found not to be in accordance with patient wishes (Bedell & Delbanco, 1984; Starr, Pearlman & Uhlmann, 1986).

Physicians have assumed that discussing and making medical decisions regarding death with elderly patients may lead to increased fear and anxiety, suicidal ideations, or decreased hospital care for those patients who choose nonresuscitation (Angell, 1984; Bedell & Delbanco, 1984; Lo, Saika, Strull, Thomas & Showstack, 1985). Despite these assumptions, a 1986 survey of hospitalized elderly patients concluded that nearly half of the patients were unaware of the code–no code practice, and most of the patients would have welcomed an opportunity to discuss their views and position (Gunasekera, Tiller, Clements & Bhattacharya, 1986). However, physician assumptions prevent such physician-patient discussions and interfere with patients' rights to participate in a serious medical decision involving them.

This study intends to empirically test these assumptions of negative patient reactions, and investigate positive outcomes when involving patients in discussions and decisions regarding their care following a cardiac arrest.

Methodology—This project has just begun. The methodology will involve a randomized control group research design to test differences in patient reactions to the CPR/DNR discussion. Two hundred physicians are being surveyed for their opinions of older patients' reactions to a physician-initiated DNR discussion. This information will be used to finalize the choice of dependent variables for the experiment. Currently, selected areas of investigation will be changes in death anxiety, general anxiety, and depression. Potential positive outcomes are: increased satisfaction with hospital care, increased sense of control over medical decisions, and increased confidence with the attending physician.

XV. Sensory Aids

A. Blindness and Low Vision

1. General

Identification of Differential Costs and Time Usage of Blind and Visually-Impaired Persons

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Purpose—The aim of this project is to answer the following research questions: 1) Are there differential monetary costs and time utilization patterns for blind and severely visually-impaired persons and in what categories do these differential costs and time utilization patterns occur? and, 2) Are they associated with particular lifestyles, life stages, and environments?

Progress—A series of four telephone surveys of 375 persons has been completed to elicit information from blind and visually-impaired persons and their sighted cohorts on educational background, employment history, visual disability, reading, mobility, job modifications, living arrangements, and income and expenditures. A fifth interview was conducted in October, 1988. Data from the interviews is being coded and entered for statistical analyses. Results of the data interpretation will be available in 1989.

Identification of Job Tasks and Management Practices Performed by Blind and Visually-Impaired Persons in the Operation of the Business Enterprise Program

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Purpose—The Randolph-Sheppard Act of 1936 (as amended) authorizes business programs operated by blind or visually-impaired persons licensed by state agencies. This study addresses: 1) the need to identify those job-related duties actually performed by licensed business operators under this program; and, 2) a review of existing training opportunities for licensed business operators through state licensing agencies. The results of the research project should provide state licensing agencies with information to assist in the design of upward mobility training programs for blind and severely visually-impaired businessmen and women operating programs under the Randolph-Sheppard authority.

Progress—Following literature review, instrumentation development, and pilot testing, a telephone survey was conducted. Blind business operators in cafeteria locations, snack bar and other locations, and in vending facility locations were asked 71 questions related to the operation of their business. Participants were licensed operators from five states in five different ED Federal Regions and represented approximately 8 percent of all blind business men and women in the U.S. Participant states submitted their training program curricula for review. All data and information was coded for computer entry and analysis conducted. A report of the study has been written and is in press.

Identification and Classification of the Career Transition Problems of Blind and Visually-Impaired Youth

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Purpose—The purpose of this project is: 1) to identify and classify the career transition problems of blind and visually-impaired youth in transition from school to work; and, 2) to outline strategies that can be used by youth agencies, service providers, families, and employers to assist youth in making successful transitions.

Progress—Following a literature review, an interview guide was developed for use in data collection during 4 site visits. The first of these site visits is in progress.

Identification of Work Assessment Technology Needs

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Purpose—The purpose of this project is to locate and describe currently available work assessment technologies which can be reliably and validly used in their present formats with blind and visually-impaired persons. Recommendations will also be made to users and manufacturers on how existing work assessment devices can be modified to meet the needs of rehabilitation and educational professionals. Needs for norm development and reliability and validity studies will be identified. Career options for blind and visually-impaired persons for which work assessment technology is not available, and specific career options for which there is a need for work assessment technologies will be outlined.

Progress--Research literature, work assessment manuals, and other manufacturer-supplied information was reviewed and organized to identify any reliability and validity studies available on samples of blind and visually-impaired persons. The statistical results and other information about the work assessment devices were entered into a computerized data bank for rapid retrieval and comparison among the various assessment systems. A draft report addressing the five issues outlined above was circulated among 10 experts in the subject area. These 10 people were asked to review and critique the draft report, offer suggestions for revisions, assist in identifying career options for blind and visually-impaired persons for whom there is no appropriate work assessment technology, and identify career options for which work assessment technologies are needed. Computer software that accesses information on the available work assessment instruments was developed for use by practitioners in the field.

Results—Results from this study, a technical report and monograph, are being prepared. The *Work Assessment Database,* which consists of three diskettes and a user's manual, is available form the MSU/RRTC for use with an IBM-PC system and PC-FILE III.

Expansion and Enhancement of the National Blindness and Low Vision Database

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Purpose—The purpose of this project is: 1) to expand the MSU RRTC National Blindness and Low Vision (NBLV) Database to approximately 1,000 cases by adding recently-closed cases; and, 2) to increase the national representativeness of the NBLV Database by expanding the geographic range of the states sampled. The NBLV database is designed to provide extensive information abstracted directly from case files by a trained data collection team. The information on each case includes case service and demographic data, such as that from the R-300 or R-911 form, running record information such as multiple disabilities, use of aids, mobility training, occupational history, facility and counselor proximities, and specific service expenditures and results in over 250 client variables for each case. The information can then be analyzed in various ways to provide extensive descriptive information on client characteristics and service delivery patterns, and can be used to determine what factors and activities of state and private vocational rehabilitation agencies contribute most to the enhancement of employment outcomes of blind and visually-impaired individuals, as well as early prognostication of client outcome. The increased sample size will ensure that all statistical estimates will be more accurate than with a smaller sample. Also, more varied and larger special population subsamples will be available for statistical analysis. This specific project increases the database by adding proportional quota sampled cases from the states of New Jersey for FY's 1984, 1985, and 1986; and from Arizona, Mississippi, and Washington for FY's 1985 and 1986.

Progress—Site visits for data collection have been completed. Coding, cross-checking, supplemental coding of jobs and disabilities, unemployment rates, etc., and data entry tasks are in progress preliminary to entry of the new data into the NBLV database. Program documentation has been updated to accommodate the new cases. Summary frequencies and descriptive statistics are being produced to describe the database. A brief annotated index report and descriptive statistics in computer printout form will be available for dissemination.

Optimal Presentation of Text-Based Computer Screens to People with Visual Impairments and Blindness

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of these studies is to understand the effects of different levels of control and types of presentation on the feedback of verbal information from text based computer screens. The first study in this project area will investigate the effect on performance of different levels of control over direction and speech rate of synthesized speech in reading long text passages. Performance in these experiments is defined as the ability to comprehend the meaning of the text in terms of the time necessary to read the text to a specified level of understanding. These experiments will be used to direct the development of future screen reading or other synthesized speech output equipment for people with blindness.

Progress—The research instrument is being constructed and the final design of the test materials prepared. Part of the research instrument consists of a specialized hand controller that will be used by subjects to direct the speech of the synthesizer when reading the test materials. The speech synthesizer which is used to present the text materials to the subjects is a DECtalk speech synthesizer from Digital Equipment Corp. It was chosen because of its high-quality speech and the ability to determine what it is speaking at any particular time. An Apple Macintosh computer provides the computing capability to create the experimental conditions and store the text materials.

Data for this experiment will be collected on the amount of time taken to complete the reading task and the level of comprehension the subject attained in that time. Additional data analysis will assess the behavior of the user when manipulating the hand controller to control functions and rate of speech feedback of the synthesizer.

Sensory Aids for the Blind and Visually Impaired

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Sponsors: *The Smith-Kettlewell Eye Research Institute; National Institute on Disability and Rehabilitation Research*

The following are summaries of some of the past year's projects of the Smith-Kettlewell Rehabilitation Engineering Center, with support from the National Institute on Disability and Rehabilitation Research.

Touch-Pad Computer Access System ("SKERF-Pad")

Purpose—The "SKERF-Pad" is a talking computer-screen reader for the blind which uses a touch-pad to represent the screen. This concept, developed by our consultant, Mr. William Loughborough, is a revolutionary step forward in computer access for the blind. It allows the contents of any desired part of the screen to be "read" in synthetic speech by pointing to the corresponding area on the touch-pad. A specially-designed overlay (produced by vacuum thermoforming) is used on the touch-pad to guide the user's fingers along raised horizontal lines corresponding to lines of screen text.

Progress—This year, the software has been converted to a resident program for IBMs and clones, and the resulting system has matured into a product that is being successfully used by an employee of the California Public Utilities Commission in San Francisco, CA. Her suggestions have contributed to new features and an improved touch-pad overlay design.

With the current version of the device (1.14) the user can instantly read any character or word at any position on the screen, read the balance of the selected line, the balance of the page (screen), or review the last 5 characters that were typed in. In "words" mode, one can easily read either a word, a line, a page, or a column of figures (as on a spreadsheet). Also, the position of the "voice cursor" can be spoken as coordinates (as can any point touched in "coordinates" mode), and the screen cursor can be moved to the voice cursor.

Compatibility with WordStar, PC Write, Lotus 1-2-3, and DOS has been proven, and it will soon be tested with SideKick and other resident programs. Beta tests are being conducted by blind users including the Research & Development Committee Chairman of the National Federation of the Blind. Evaluation is also under way at the Central Blind Rehabilitation Center of the Edward Hines Jr. VA Hospital in Hines, IL.

A true advantage of the SKERF-Pad is its cost: the Touch Window and the speech synthesizer are commercial devices which can be obtained from their manufacturers for a total cost of about $500. The remaining essentials—a disk containing the SKERF-Pad software and a Thermoformed overlay for the touch-pad—can be purchased for $50 from William Loughborough, Santa Rosa, CA 95401.

Smith-Kettlewell Volatile Braille Display

Progress—The new low-cost refreshable or "volatile" braille display developed in our laboratories has progressed rapidly. We are pleased to report that major sensory aids manufacturers are interested in commercial production of the system. The device uses low-cost electromagnetic technology combined in a unique proprietary design to result in a simple-to-manufacture unit which eliminates the need for fabrication of the many different parts required by currently-manufactured displays.

Preliminary Results—As a result of our mechanical and electrical tests on the first prototype, a number of problem areas were identified for attention. In seeking solutions to these problems, a radical improvement and simplification of the design was achieved and an upgraded prototype constructed.

A new 3-cell prototype was built to make certain these radical design changes described would result in a workable device before attempting a full-sized version. Initially, one full cell of this prototype was wired up with coils and driving circuitry for testing.

The upgraded prototype has been tested by 8 blind individuals with the following criteria and number reporting difficulty: 1) dot height and resistance to deformation: 2; 2) dot uniformity and uniformity of background: 1; and, 3) degree of sideways play, speed of operation, display temperature, tactile comfort: 0.

The results indicated that the main factors needing modification involve the perceived height and the resistance to deformation of the dots. Those subjects who expressed reservations on this score agreed that the difficulty would be obviated if the ends of the braille pins were made smaller in diameter, thus making the dots "sharper" and improving readability.

Flexi-Meter

Purpose—The Flexi-Meter is a universal job instrumentation system for the blind under development in our laboratories. The system will enable information from many different measuring devices used in various job situations to be processed and presented auditorially for the blind employee.

A number of special functions will be available for use when appropriate. These will include, but are not limited to: automatic indication (beep) that a reading has exceeded a preset value, and automatic reading taken upon occurrences such as changing data.

An engineering prototype of the Flexi-Meter has been designed and constructed. After testing the basic boards, the prototype was packaged for testing in and out of the laboratory with various transducers. The unit meets or exceeds all original specifications and has both physical room and memory space for expansion as necessary. Extensive software development has taken place, and the device has been bench-tested and demonstrated in our laboratories and at conferences. It has been interfaced to a weather station as a test and demonstration model.

Braille Notetaker

Purpose—The Note-a-Braille is a nonsophisticated, low-cost, pocket-sized notetaker for people who know the standard braille-writer keyboard. Information is written into internal memory via an 8-dot braille keyboard (the 2 extra dots, operated by the little fingers, permit single-stroke entry of upper case letters and control characters). To minimize cost, no readback features or editing capabilities were incorporated in the design. The unit emits faint clicks, as the keys are operated, to assure the user that entry is successful. Information is retrieved by "uploading" the Note-a-Braille's memory into a computer through its standard Centronics parallel port. In most cases, a parallel-to-serial converter will be necessary to convert this parallel information into serial form; a number of such converters are commercially available for about $100.

Results—A production version of the Smith-Kettlewell Note-a-Braille II is now being manufactured by HY-TEK Manufacturing Company, Inc., Sugar Grove, IL 60554.

"Dexter": A Mechanical Fingerspelling Hand for Deaf-Blind Users

Purpose—The concept of the Dexter system is to provide communication for the deaf-blind through the application of robotics in the shape of a finger-spelling hand. The project is being carried out in conjunction with the VA Rehabilitation R&D Center in Palo Alto, CA. Recent efforts on the project have been directed toward refining Dexter to simplify the finger movements in preparation for more extensive evaluation by deaf-blind subjects. Dr. Deborah Gilden of our staff defined the letter-pair transition movements, and Dave Jaffe of the VA Rehabilitation R&D Center provided the programming to eliminate the neutral position between all letter pairs, making the system faster and more fluid.

A second goal has been to explore the feasibility of simplifying the hardware configuration of Dexter. A new version of the hand has recently been completed as a student project at Stanford, and is now about to be tested by our staff using deaf-blind subjects.

Progress—Progress has also been made toward another goal: interfacing Dexter to another computerized system for deaf-blind people. In October of 1987, Dexter was interfaced with the Talking Glove, an expressive device for deaf and deaf-blind people developed by Jim Kramer, a graduate student at Stanford University. This 2-way communication capability was demonstrated by a deaf-blind user at the California State University, Northridge, Conference on Computer Technology, Special Education and Rehabilitation.

Dotless Braille Reader

Purpose—The concept of the Dotless Braille Reader (a device for presenting braille to those with poor tactile sensitivity) is to use a braille keyboard in which the keys lift the user's fingers up to transmit braille information.

Progress—*Full-Scale Prototype Design and Fabrication.* Our pre-prototype unit consisted of only 2 buttons—one which moved up and one which dropped down. We fabricated it to determine which direction of excursion was preferred by blind users. The choice of upward motion was virtually unanimous. We subsequently completed fabrication of a complete-cell prototype Dotless Braille Reader. We chose to build an 8-button rather than a 6-button version to allow the reader to access computer braille. During the presentation of standard materials, the extra buttons (one on each end) remain dormant. The Reader is currently interfaced with an 8-key electronic braille keyboard, from which it receives information.

Results—*Feasibility Evaluation.* Informal usage by blind staff and students at the Smith-Kettlewell Rehabilitation Engineering Center, none of whom have degraded tactile sensitivity, indicated that: 1) this method of reading braille code kinesthetically does allow for the transfer of the information; and, 2) at least initially, this is a much slower process. This latter finding is not at all surprising. In fact, we have the impression that this multi-finger system of reading requires an entirely different skill from the standard braille reading method. It may be that a new motor-cognitive neural complex is involved in interpreting kinesthetically-received information compared to tactilely-received information. Paul Bach-y-Rita, MD, an expert on brain plasticity and sensory substitution, concurs with this hypothesis. We are determining how much improvement in speed is achieved by skilled braille users through a limited amount of practice with the Dotless Braille Reader. We have now prepared for extensive testing with deaf-blind subjects and those possessing reduced tactile sensitivity. This will allow us to determine the system's apparent effectiveness with different population groups, its probable applications, potential production costs, and potential for commercial exploitation.

Functional Vision Assessment in Usher's Syndrome

Purpose—We have completed a pilot study to develop improvements in the clinical examination of deaf patients with progressive retinal disorders (usually Usher's Syndrome). The examination of these patients is presently often inadequate because of: 1) the communication problems that exist among the patient, the interpreter and the ophthalmologist; and, 2) incomplete current knowledge about the eye disease and the exact nature of the retinal changes it produces. Our first priority is to address the communication problem so that greater understanding of the other problems can follow.

Progress—In this effort. we are collaborating with Dr. Lea Hyvarinen, a member of our Scientific Advisory Board and internationally renowned expert in low vision and the deaf-blind. Dr. Hyvarinen has informally explored combinations of conventional sign language and other special tactile signs and cues for use in the specialized environment of the ophthalmologist's office during an eye examination. This work has revealed the need for re-educating, with suitable training materials, the patients, sign language interpreters, and medical specialists to improve communication. Study materials for the patients and interpreters have been written, and video films depicting the communication process during the visual examination have also been developed as training tools. Full results of the study will be published shortly.

Flexi-Formboard

Progress—The Flexi-Formboard is the first educational toy developed at the Smith-Kettlewell Rehabilitation Engineering Center to achieve the sought-after goal of commercialization. This electronic formboard is scheduled to be manufactured and distributed by Adaptive Communications Systems, Inc. ACS is a rapidly-growing company which specializes in communication aids for non-speaking children and adults, and has recently added adapted toys for physically disabled children to its product line. We are most pleased that ACS is providing the mechanism to make the Flexi-Formboard available to disabled children.

Tact Tell System

Progress—A prototype Tact Tell Map has been fabricated and represents, to our knowledge, the world's first "talking map." It comprises a 6-piece wooden puzzle map, an Apple Computer, a speech synthesizer, and appropriate software. The pieces represent Greenland, Canada, Alaska, the remainder of the United States, Central America, and South America. To accommodate users with low vision, each piece is painted a high-contrast color to make it easily differentiated from other pieces and from the blue "water" background.

The user may choose any of 5 levels of difficulty. The simplest level is designed for very young sighted children or others who have limited vision, as it requests the user to insert geographical pieces by color. The name of each piece is incorporated into the feedback from the computer via the speech synthesizer in response to the insertion of each piece.

The map circuitry was designed to detect and store any transitions that occur to the puzzle piece locations on the map. Each puzzle piece location on the map has a magnetically-actuated proximity switch; each puzzle piece has a magnet embedded within. The magnet activates the proximity switch when the piece is in the puzzle, and the circuitry records this transition for detection by the program.

Photographic Vision Screening Methods

Purpose—Our research efforts in the field of new photographic vision screening methods for infants have made major progress. Our studies over the past 2 years indicate that the laboratory version of the system, using a 35mm camera with a catadioptric lens, can provide useful and accurate information on the state of refraction and astigmatism of the infant eye, while also highlighting other vision problems. The new Polaroid version of the device, described below, is not intended for fine measurements but for screening use by pediatricians, giving them the capability of detecting anomalies in infants' vision during routine office visits. Both of these versions have possible applications by paramedical field teams in remote rural areas and in developing countries where medical resources are scarce. An additional version, the feasibility of which is now being explored, would widen the possible target population further by providing almost any camera with an inexpensive attachment for performing photo-screening.

Progress—During the current year we have completed the design, construction and calibration of the Polaroid photorefractor. The device consists of a metal periscope attachment for a Polaroid Spectra camera. The periscope directs light from the camera strobe flash to a precisely calibrated location inside the entrance pupil of the camera's optical system.

We have developed, in collaboration with Dr. Wolfgang Wesemann, a rigorous analytic description of the optics of off-axis photorefraction. Previous theoretical treatments had only discussed the case of spherical refractive errors. Our description includes not only the spherical case, but also the photorefraction of astigmatic eyes. This analysis has relevance to the general design of any off-axis photorefractor and has pointed out specific weakness in a commercially available screening device.

Preliminary Results—Initial testing in our laboratories pointed out the need for certain improvements such as the use of higher quality mirrors and the incorporation of an LED light source on the camera to attract the infant's attention. These modifications have been incorporated. Alignment of the camera with the subject's pupil was found to be relatively critical. The optical analysis provided by Dr. Wesemann has assisted our understanding of this feature, and possible methods of reducing the effect of malalignment are under consideration. Provided correct alignment is maintained, however, successful operation is assured. The sensitivity of the device to refractive error can be set to the desired level by adjusting the occlusion of one of the mirrors. For the type of screening applications we envisage, we set the device to detect differences between eyes in excess of one and one-half diopters.

Since mid-1987, the Polaroid photorefractor has been undergoing field testing in the pediatric clinic at the Kaiser Permanente Medical Center in South San Francisco, CA, to assess its potential utility in a pediatric office environment. We are currently screening a large group of infants under 1 year of age with the Polaroid system. Follow-up ophthalmological exams are being conducted in a double blind fashion by Charlene Hsu, MD. Thus far, the device has proven to meet design expectations for sensitivity to refractive error.

Hybrid Fresnel-Conventional Magnifier

Purpose—We have completed the design and fabrication of our first prototype Fresnel-conventional low vision reading magnifier. The concept of this device is to combine the advantages of clarity and high contrast provided by conventional optics with the light weight and wide field of view made possible by Fresnel technology.

Conventional magnifiers used in reading by low vision patients give only a restricted field of view, dictated by the size and weight of the optics for any desired magnifying power. The magnifier occupies only the central visual field, which can create difficulties for those patients with scotomas partially or completely occluding this area. These patients may need to fixate on a point outside the magnifier in order to project the magnified image on a "good" area of retina—a difficult task. The small magnifier size also requires constant scanning, which is made more difficult by the fact that the magnified information is taken "out of context," since there is no indication of the format of surrounding text.

Progress—Large Fresnel magnifiers can overcome these problems, but the images they provide are generally regarded as optically inferior. Consequently, we designed a lens with a conventional optical center (to maximize clarity of the actual words and letters being read on the best part of the retina) and a large-diameter Fresnel surround (to provide wide field of view for ease of fixation and scanning).

Illumination Problems in Vision

This work is being carried out in collaboration with Alan Lewis, OD, PhD, who joined our staff for a one-year sabbatical in 1987.

Battery-Powered Multi-Purpose Lighting System

Progress—We have designed a battery-powered, low-voltage supplementary lighting system which incorporates the quartz-halogen MR16 technology (and, upon availability, the MR11). These 12-volt systems employ precision reflectors which are available in several beam patterns and which utilize dichroic coatings to alleviate much of the infrared problem common with conventional incandescent sources. The compact, light-weight and efficient system is suitable for mounting on a head frame, loupe, or hand magnifier to provide localized illuminance of up to 20,000 lux at a working distance of 2 feet. The precision optics give excellent beam control and therefore minimize glare to others.

Fiber-Optic Illuminator for Use with Hand-Held and Stand Magnifiers

Purpose—Low vision patients who rely on short focal-length visual aids have great difficulty obtaining sufficient illuminance on the visual task because conventional lighting systems are blocked either by the device itself or by the user's own body shadow. While battery-powered incandescent or fluorescent systems have been used in some magnifiers to help alleviate this problem, they often provide insufficient light for persons with high illuminance requirements and introduce veiling reflections which obscure specular tasks.

Progress—We have synthesized a preliminary design which uses a highly efficient 70-W metal-halide source (>70 lm/W), with fiber-optics to deliver the light to the magnifier, and a 3-mirror optical system in combination with a Fresnel lens to distribute the light on the work surface. This new lighting technology is capable of producing very high illuminances, excellent color, and is glare-free. The very small size of the metal halide arc allows fiber-optics to be employed to remove the source itself from the immediate vicinity of the user, thus eliminating the major safety hazard and annoyance of heat from incandescent lamps.

Low-Contrast Acuity Charts

Progress—We have begun the development of an innovative low-contrast acuity chart, designed to give the clinician a rapid measure of visual contrast sensitivity. Detection of low-contrast and low-luminance targets are important parameters in assessing the functional vision in the partially sighted. These functions are thought to be particularly important in mobility and other daily tasks. Currently, the measurement of these performance factors requires multiple tests of some complexity.

Our new concept combines the measurement of low-contrast and low-luminance vision performance into one eye chart of proprietary design, allowing a single and rapid test of the patient's visual performance under conditions of reduced contrast and luminance. Preliminary tests of the new concept have proven successful, and fabrication of a new version for larger scale testing is under way.

Model Rehabilitation Engineering Service

Progress—We have established a privately-funded Rehabilitation Engineering Service to provide custom-designed sensory aids for the blind and low vision populations on a user-fee basis. The first devices from this program have been successfully designed, fabricated, and delivered, and expansion of the program is under way. We have secured the cooperation of a software developer who has agreed to act as a subcontractor for this service, and we are investigating the inclusion of an electronics training program on a fee-for-service basis (based on our experience with our earlier Blind Technicians' Training and Research Program). This privately funded Rehabilitation Engineering Service has also supported the printing and distribution costs for the *Smith-Kettlewell Technical File.*

We anticipate increased demand for this service as the provisions of the 1986 Rehabilitation Act Amendments are implemented more fully by state departments of rehabilitation.

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A. Blindness and Low Vision

2. Mobility Aids

Clinical Application Study of Training Techniques and Devices for the Blind

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Purpose—The purpose of this project was to determine the efficacy of applying a secondary task methodology to the evaluation of the mobility performance of blinded veterans. Previous work by the authors demonstrated that measurements of critical events such as bumping or stumbling did not adequately describe the mobility task. We hypothesized that the introduction of a secondary task (reaction time) under different conditions of mobility (sighted guide and independent travel) would demonstrate that the performance of the secondary task would decrease as the requirements of travel increased.

Methodology—In this experiment, 20 blinded veterans currently enrolled at the Eastern Blind Rehabilitation Center (EBRC) were subjects. A Tandy PC-6 pocket computer was programmed to generate an auditory stimulus, a "beep," at irregular time intervals. The computer, when squeezed, would record the time from the beep to the squeeze response. The output included the number of trials, a response count, the mean score, and standard deviation.

Each subject was introduced to the test strategy and allotted a practice interval. A 5-minute baseline was established followed by random assignment to both a 5-minute independent indoor walk and a 5-minute walk with a sighted guide. The route required indoor travel in hallways, through doorways, and on stairs in an area familiar to the subjects.

Results/Implications—A repeated measures analysis of variance (ANOVA) $F(2,38)$ $p<0.05$ demonstrated significant differences between the groups. *Post hoc* analysis revealed that all three conditions were significantly different from each other. Standard approaches to the assessment of mobility performance involve measurement of problem behaviors, such as bumping, stumbling, or crossing the street at inappropriate times. The major limitation of this approach is the relatively infrequent number of these behaviors which are exhibited during a mobility evaluation.

This research hypothesized that one approach to evaluating travel skills was to quantify the amount of effort expended during travel. It was specifically hypothesized that comparisons of seated reaction time would be different from travel with a sighted guide (physical effort) and these would each be different from independent travel (cognitive effort). The results demonstrate that the effort required to travel with a sighted guide or independently is significantly slower than when seated. The effort involved with independent travel is also significantly greater than the effort involved with sighted guide travel. These findings suggest that the use of a secondary task for the assessment of mobility performance holds promise for documenting the improvement of clients involved in mobility training.

Evaluation of Electronic Travel Aids (ETAs) for Visually-Impaired Individuals

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C406-RA)*

Purpose—The objective of the study was to learn more about the use of Electronic Travel Aids (ETAs) in the United States by blind adults, with emphasis on the personal and environmental factors that relate to particular patterns of aid use. A second objective was to determine whether the pattern of use of the long cane and the dog guide was similar to use patterns for ETAs. Professionals in orientation and mobility training for blind persons generally believe that ETAs are used by a small percentage of the individuals who have been trained on the devices. Another important outcome expected of this study was to determine whether or not this perception was accurate.

Progress—During the 24-month study, 284 blind individuals trained to use ETAs were interviewed by telephone. The interviews lasted approximately one hour, and allowed researchers to obtain data on demographic variables, travel patterns, and perceptions of the benefit of ETAs. Each of the participants in the study had been trained to use at least one of four ETAs (i.e., Laser Cane, Mowat Sensor, Pathsounder, and Sonicguide).

Results—Results of the interviews indicate that 43 percent of the individuals trained to use any of the four ETAs have used the aid in the last 30 days, and thus are current users by the definition established for this study. This percentage is substantially higher than that expected by orientation and mobility (O&M) practitioners. Half the users reported much safer travel in an unfamiliar area since beginning ETA use, and 90 percent reported fewer cane and body contacts. Approximately half of the users reported increased confidence and efficiency in travel as a result of aid use, with a similar percentage reporting more frequent aid use in an unfamiliar area. Not surprisingly, avoidance of obstacles, and detection of distance of direction to objects, were the situations where the aid was rated to be of greatest assistance in travel. The Laser Cane was the device reported used in the past 30 days by the highest percentage of individuals trained (66 percent). The Mowat Sensor, Sonicguide, and Pathsounder were used by 59 percent, 25 percent, and 22 percent, respectively, of those trained on each device.

In regard to the 35 percent of individuals surveyed who were former users, responses to questions about reasons for discontinuance tended to be somewhat idiosyncratic. Each of 5 reasons were reported by 10 to 15 percent of the interviewees. They were: declining health, decision to change to another aid, design problems, changes in environment, and general or unspecified dislike.

Future Plans—Preliminary analysis of the user/former user data revealed that users tended to be older than former users, tended to be trained within the last 9 years, and were likely to be older at time of training. Further analysis will be conducted to explore these findings in greater detail. No differences between users and former users were found on ratings of training quality or ease in learning to use the device. Veterans and nonveterans did not show different patterns of use or former use. All interviews with ETA-trained individuals has been completed. Publications of the results of this study is anticipated in 1989.

Minimal Information Sensor System: A Mobility Aid for the Visually Impaired

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Sponsors: *VA Rehabilitation R&D Center Core Funds; Western Blind Rehabilitation Center*

Purpose—The most commonly used mobility aid for the blind, the long cane, provides no protection above the waist. Obstacles present in the environment above the waist, such as overhanging tree branches, are not detected prior to contact. The development of an effective aid to detect potentially hazardous obstacles in the environment above the waist could increase the safety and confidence of blind travelers.

The long cane has proven to be an effective and low cost solution for handling one of the most dangerous aspects of travel for a blind person—the detection of drop-offs such as stairs and curbs. The cane also detects low obstacles and affords some protection against obstacles located below the waist. However, the entire upper portion of the body remains vulnerable to protruding obstacles above waist height. Common examples are signs hanging to the side of a post, scaffolding, trucks sitting crosswise blocking a sidewalk, boards and pipes extending from a vehicle, and overhanging stairways. Of particular concern is the head area, the portion of the body most likely to be damaged seriously by such an encounter.

Electronic travel aids for the visually impaired, which supplement the use of the long cane, have been developed over the last 25 years. Many of these aids are capable of detecting obstacles above the waist, when used in addition to the long cane. However, these aids have more extensive functions, and are not designed primarily for head-high obstacle detection. Electronic travel aids are currently used by a small number of visually-impaired travelers (1 to 2 percent). Generally, electronic aids are either cumbersome in size, cosmetically unattractive, expensive, or use a coded format that is difficult for the user to learn and interpret while traveling.

A simple electronic device that would emit a warning when a head-high obstacle is encountered at a relatively close distance (3 to 5 feet) would enhance the safety and confidence of blind travelers. Several criteria must be met for the aid to be both effective and accepted for use by the visually-impaired traveler. The aid should be small in size, worn on the body rather than hand held, cosmetically acceptable, unobtrusive to others in the environment, without visible wires and power packs, easy to use, reliable, and low in cost (under $200).

Progress—Preliminary studies have included simulation experiments using human subjects, trials with existing electronic travel aids, assessment of the needs of visually-impaired travelers, and a survey of existing aids to determine if any can be used as the hypothesized aid. This information has been used to determine the specifications of a simplified electronic travel aid to be used in the development of a prototype device. Devices that meet or partially meet the requirements specified will be tested by visually-impaired subjects traveling routes in the community under the supervision of orientation and mobility instructors.

Results—Simulation experiments have been completed that demonstrate the effectiveness of a simplified warning system for blind-folded travelers while using a long cane. A survey of orientation and mobility instructors in the field of blind rehabilitation indicates a need for the hypothesized device and further defines target characteristics. This preliminary work is being used to apply for funding that would allow testing of a prototype device to determine the effectiveness of this type of warning system.

Future Plans/Implications—Pilot project funding is being sought for further research, including fabrication and testing of a prototype head-high obstacle detector.

Measuring the Spatial Layout Knowledge of Visually-Impaired Adults

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Sponsor: *Rehabilitation Research and Development Center, Edward Hines, Jr. VA Hospital*

Purpose—The spatial cognition of visually-impaired travelers must be understood if the techniques for training and devices used for orientation are to be optimized. At present, knowledge about spatial cognitive processing is limited even for sighted travelers and generalization from sighted to visually-impaired travelers is not clearly possible. An essential component of this research is determining a valid and reliable measure or measures of the spatial knowledge of the visually-impaired traveler.

Progress—In the last year, five measures of spatial knowledge have been assessed in two studies. These measures include: relative distance estimates, absolute distance estimates, direction estimates (or pointing), hand-drawn maps and map boards. Despite previous assumptions that absolute distance estimates would be difficult and inaccurate for visually-impaired persons, subjects in these studies have shown generally acceptable levels of consistency in their distance estimations. Because this measure is less time-consuming and causes less strain for the subject, it would appear to be a measure of choice. Further studies are underway to complete the process of comparing measures of spatial cognition.

Future Plans—All the above work was done in familiar environments; additional work is underway to examine the processes involved in learning an unfamiliar environment. Experiments are restricted at this time to large indoor environments, but will be expanded to an outdoor environment in future studies.

Orientation and Mobility for Blind Adults Over 60 Years of Age

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Sponsor: *Office of Special Education Programs, Department of Education*

Purpose—The purpose of this three-year study is: 1) to develop a valid and reliable instrument with which to assess orientation and mobility skills of blind persons over 60 years of age; and, 2) to develop and validate an instructional program in orientation and mobility for use by rehabilitation teachers, health care and nursing home staff, nurses, aides, aged visually-impaired person's families, and volunteers with this population.

The purpose of the assessment instrument and the eventual training curriculum is to provide aged blind persons with the necessary orientation and mobility skills to move around as independently as possible in their immediate living environments. With safer and more efficient travel skills, aged blind persons threatened with placement in a less independent living situation, could remain in their current living situation leading fuller and more productive lives. The use of these instructional materials by laypersons and/or professionals in the field of blindness should vastly improve the independent travel ability of aged blind persons because of the acute shortage of trained mobility instructors.

Progress—Scoring procedures were developed that would allow a layperson or professional to score each item of the assessment instrument correctly. These procedures enable the person administering the instrument to compare the performance of the aged blind person to a series of pencil drawings depicting acceptable versus unacceptable techniques.

The instrument was designed to be sensitive to the needs of a heterogeneous population of aged blind individuals. It also was designed to meet the criteria identified in the grant specifically related to the five domains of orientation and mobility training: sensory, motor, orientation, concepts, and mobility. After the initial drafts of the instruments were critiqued and revised by the project staff and consultants, the instrument underwent validation by nationally recognized experts in the fields of blindness and gerontology.

Results—Four aged blind persons, with an average age of 75 years and a range of 70 to 79 years of age, were selected to participate in the pilot phase of the study. All four subjects were severely visually-impaired, with light perception being the most frequent diagnosis. In addition, four volunteer test administrators were also selected to participate in the pilot testing of the instrument. Each of the administrators was either a recruited volunteer or a friend who agreed to participate in the pilot testing. The administrators were unfamiliar with the techniques of orientation and mobility. After the pilot study results were analyzed, the assessment instrument was revised to meet the needs of subjects and to clarify the instructions for the volunteers.

Future Plans—The goals of our investigation during the second year are to continue to validate the assessment scale with which to assess orientation and mobility skills and to develop and validate an instructional program in orientation and mobility for visually-impaired persons over 60 years of age.

The instructional program will be pilot-tested to refine and clarify content items and administration procedures. The revised instructional program will be validated under experimental and control treatment conditions with 40 subjects. The assessment instrument will be used to test these 40 subjects to measure any gains in the orientation and mobility skills.

This study will be replicated in the third year of the project with experiment and control subjects at a different location. The instructional materials will then be submitted for publication if the results show significant gains by the participants.

Development and Evaluation of a Feeler Stick for Visually Disabled People

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project was to develop and test a feeler stick for visually disabled people that could be folded or collapsed as small as possible.

Results—The research has resulted in the prototype of a telescopic stick with a new kind of quick lock. However, this construction had a number of disadvantages which, within the limitations of the available funds, could not be corrected sufficiently, despite several improvements.

This study was conducted in cooperation with TNO Product Centre.

Development of a Reflex Detection Stick as an Aid for the Mobility of Blind People

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purposes of this study are: determination of the need of blind people for a reflex detection stick (a device mounted on a stick which gives an acoustic signal if moved over a white line);

determination of an effective way to apply the necessary paint lines on pavements; and, the execution of a user test in order to assess the effects in practice.

Progress—A trial track was installed at and around the railway station in Enschede. With the help of the system, the testees indeed proved to find their way more easily. The prototype and the painting materials used were satisfactory.

Future Plans/Implications—The apparatus will now be mass-produced in small numbers for further tests in which four municipalities will co-operate, and research will now be focused on long-term usability. It will also be considered whether the system can be included in social security.

This project was implemented with the cooperation of Twente Technology Transfer; Province of Overijssel; Dutch Rail; and various municipalities in The Netherlands.

A. Blindness and Low Vision

3. Reading Aids

Establishing Design/Operational Features of Portable Blind Reading Aids

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C378-RA)*

Purpose—This project has four goals: 1) to establish unmet needs for reading aids among blind persons; 2) to determine where new components and systems are appearing to help meet those needs; 3) to establish experimentally the design and operational specifications for the next-generation reading aid; and, 4) to utilize and disseminate the information acquired promptly. The two unifying purposes of these coordinated activities are: 1) to provide the information needed to ensure that the next-generation reading aid is more useful, affordable, and widely-accepted than currently available devices; and, 2) to prepare the ground thoroughly for the design, construction, and preliminary evaluation of a next-generation reading aid prototype.

Progress—A "general user questionnaire" has been completed and administered by telephone to approximately 150 blind and visually impaired individuals in three groups: veterans (of working or retirement age), non-veterans (of the same age groups), and students (in the college age range of 17-23). Of these persons, approximately 70 were identified as being "experienced users of technology," meaning that they had a minimum of one year of actual use of some technology-based reading aid. Twenty-five of these 70 were selected at random, and were administered an in-depth telephone interview on their technology use histories, and the impact on their lives.

The survey of current technology has led to the identification of several specific components that appear well-suited for a next-generation reading aid. A series of human performance tests using our Center's reading aid simulator has been completed on blind, low-vision, and fully-sighted individuals (the latter to provide baseline measurements). The tests have allowed the investigators to measure accuracy versus speed under several conditions of feedback while a small camera is hand-tracked over lines of text, and to identify the most promising type of feedback for use in a portable workstation for blind individuals.

Results—Each of the areas of activity has yielded useful results. The questionnaires revealed significant and interesting patterns of use of reading aid technology by blind individuals, and have documented a distinct trend towards the incorporation of computers into blind persons' lives. The technology surveys and follow-up contacts have allowed us to acquire specimens of certain candidate technologies at no cost to the project, and have provided us with valuable contacts for developing additional technology-based capabilities in the near future. The human performance studies have allowed us to identify the best feedback mechanism to provide to people who are freely hand-tracking a small camera across lines of text on a page.

Future Plans/Implications—Blind individuals have strongly communicated that they want and need better devices to help them meet their reading needs adequately. In discussing their wants, they stress such concepts as functional modularity, mechanical integration, interconnectivity, and a wide range of choice of features, along with affordable cost (under $5,000) and, where portability is an issue, manageable weight (under 20 pounds). In addition, they highly appreciate the power of the computer, with its ability to acquire and store data, retrieve, modify, and display it, send it over telephone lines via modems, and produce output via voice, braille, or inkprint. The next-generation device must move in the direction of an integrated computer workstation for the blind, reducing the peripheral count, providing more functional choices, increasing the power, and lowering costs and weight over currently existing devices.

Publications Resulting from This Research

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Reading Aid Technology for Blind Persons: Responses to a Questionnaire of Experienced Users. Steele RD, Goodrich GL, Hennies D, McKinley JA, *Rehabil Technol* (in press).

Braille and Automation

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The project aims are the standardization of the symbols used in the 6-point braille, and the recording of it in the 7-point and 8-point information code, in order to electronically process braille symbols, to stimulate the use of computers by visually-impaired people.

Other subprojects include the development of: 1) practical guidelines for lay-out of braille; 2) function demands for the braille line; and, 3) 8-point braille and the recording of 8-point braille symbols in 8-bit information code.

These tasks are being performed by the standards committee under supervision of the Dutch Normalization Institute (DNI). The standards committee consists of interested parties, among whom are the producers and suppliers of aids for braille readers and representatives of interest groups.

Progress—The standard for the significance of 6-point braille symbols is complete, except for publication. The recording of 6-point braille symbols in the 7-point and 8-point information code has been defined in a design, but has yet to be extensively adapted. The lay-out of braille and the function demands of the braille line have also been defined as a design, but have yet to be published.

Eight-point braille and recording it in 8-bit information code has been finished as a design document. The document has been submitted to the international study group, but has not yet been accepted as a final design.

Braille Terminal

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Purpose—The purpose was the development of a portable, lightweight braille computer, with a battery supply and 40-character braille line, primarily for use in educational situations (transportable from home to school/course and vice versa).

Results—The development was successful by integrating a 40-character braille line, controll and coupling electronics with a portable commercial computer, Epson PX-8. The complete machine was introduced on the market as model RS-501. Because of the interference sensitivity of the braille cells, there were some technical problems, but these have been solved.

Blind users now work with this equipment. A commercial break-through has not yet occurred, because the institutes and libraries for the blind have not converted the CPM-operating system of their computers to the MS-DOS system.

Braille Line

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Development of a braille line with which the information on a computer display can be reproduced, in order to enable blind people to work with computers.

Progress—In 1987, the article was taken into production and proved to be successful. Considerable export orders were booked and cooperation with a Dutch producer of computers was also established.

B. Deafness and Hearing Impairment

Validity and Reliability of a Physiological Test of Vestibular Function

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C412-RA)*

Purpose—Balance and movement disorders associated with the inner ear are common medical complaints, affecting approximately 40 percent of the population over 40 years of age. There is a need for a well-documented vestibular test that is comfortable to the patient, simple to implement, tests horizontal and vertical vestibulo-ocular reflexes, provides useful diagnostic results, and is relatively inexpensive and fast to administer. A computer-based technique recently has been developed by the co-principal investigator, Dr. Dennis O'Leary, to fulfill these needs.

The technique, which is called the Vestibular Autorotation Test (VAT), monitors the horizontal and vertical vestibular-ocular reflexes (VOR) in the 2-6 Hz physiological range, using 18 seconds of horizontal or vertical movement with the eyes fixed on a stationary target. Eye position and head velocity information, calculated from eye position information, using a 2-point central difference deviate algorithm, and head velocity data are reduced to 100 samples from which VOR gain (eye velocity amplitude/head velocity amplitude) and phase are computed by discrete Fourier analysis, using signal-processing techniques on a personal computer.

Methodology—For the VAT to be developed as a routine clinical procedure, which potentially could replace the current electronystagmography (ENG) technique, including the caloric, tracking, and rotatory chair procedures, a broad normal database including all age groups is needed to establish the validity and reliability of the VAT. The following questions are being addressed in the 3-year study: 1) Does the VAT provide a valid and reliable assessment of vestibular function? 2) Are the data provided by the VAT more sensitive to vestibular dysfunction than are the data provided by the currently-used ENG techniques? 3) Is there a parallel age-related decline in vestibular and auditory function that can be measured with the VAT and with traditional auditory tests? and, 4) Does the VAT provide sensitive data for monitoring vestibular function of patients receiving potentially vestibulotoxic medications?

Because this study is in its first year of funding, we are currently evaluating only subjects with normal ENG results, normal hearing sensitivity for their age, and no vestibular complaints. Comparisons will be made among the results of the VAT, ENG, and audiological tests.

Preliminary Results—Thirty-four subjects have been evaluated with the VAT as of this date, and the results are reliable across subjects. From this data, the range of normal variability has been established. These norms will be used as a basis of comparison for abnormal subjects. One potential long-range application of the VAT device is to use a miniaturized version to monitor changes in vestibular function during postural rehabilitation procedures with patients who are dizzy or who have unsteady gait.

Electroacoustical and Clinical Protocols for Evaluating Assistive Listening Devices

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #C944-PA)*

Purpose—People who suffer from hearing loss do not receive adequate help from hearing aids in situations where there is background noise or where the speaker is some distance away. Hearing aids amplify all wanted and unwanted signals in their range, both the interfering background noise and the speech. Examples of distance listening where hearing aids are of limited benefit include attending church services, going to a movie or play, and watching television at home.

Assistive listening devices are very useful in both noisy and distance listening situations because they use special microphones which are placed close to the speaker, and transmit the signal directly to the hearing-impaired listener. In this way, the important message is transmitted without picking up the interfering background noise or losing the intensity of the signal because the speaker is a great distance away.

The purpose of this pilot project is to develop methods for the evaluation of these assistive listening devices to determine which of the many devices meets the needs of the particular hearing-impaired individual. The audiologist must have reliable information about how the device amplifies sound and how to evaluate the device on the patient. An electroacoustic protocol will be developed to determine how the device amplifies sound. Technical specifications will be developed that describe how much amplification is provided in the various pitch ranges and how effective the microphone and amplifier are in reproducing the signal effectively.

A clinical protocol will be developed that will measure the effectiveness of the assistive listening device while it is worn by the hearing-impaired person. The measures will include determination that the required amount of amplification is present by measuring the amount of sound in the ear canal with a miniature microphone. The ability to understand speech while wearing the device will be measured by having the person listen to words in a background of interfering noise and repeat the words heard. Patients wearing the device will also report how much they understand by judging whether or not they feel the words are intelligible. They will also judge whether or not the quality of the device is good by reporting on how pleasant the speech sounds.

Variables Affecting Hearing Aid Performance

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C337-RA)*

Purpose—The goal of this program is to complete electroacoustic and behavioral studies of the interaction of acoustic sound sources with the acoustic impedance of the ear canal and the middle ear. For these purposes, a personal computer-based measurement system (IBM-PC XT/AT) is being developed, modified, and refined.

Progress—The measurement system is configured to make magnitude and phase measurements of the performance of earphones when coupled to ears or couplers. Previous versions used these data to perform fast Fourier transform (FFT) analysis in software which compromised the speed with which data could be collected. The current system is now being reconfigured to incorporate a relatively low-cost, 2-channel, outboard peripheral with a FFT spectrum analyzer that is based on the Texas Instruments TMS 32010 digital signal processing chip for very fast spectrum computation (Rapid Systems, Inc. Model 350).

Results—During the past year, a comprehensive review was completed of the theory underlying previous attempts to measure the input immittance of the ear, to quantify the acoustic immittance of the ear canal and then to derive the immittance at the plane of the tympanic membrane. There remains a need for a valid as well as clinically and experimentally expedient method for quantifying the immittance of the residual ear canal volume.

A "two-load" method of measurement of the acoustic impedance of small transducers has been implemented and validated. Preliminary test-retest studies of a single transducer suggest that these measurements can be carried out with a fair degree of reliability. Methods of coupling a variety of hearing-aid-like sound sources to the acoustic loads are being examined and further test-retest studies are planned.

The interaction of earphone type with the acoustic impedance of the ear was assessed by studying the pure-tone air and bone-conduction thresholds of normal ears, and ears with conductive pathology, using a TDH-50 earphone and an ER-3A insert earphone. The results indicated that on the average, the two earphones produced the same estimates of air-conduction thresholds, and thus, the same estimate of the magnitude of the air-bone gap. An examination of the individual subject data, however, suggested that factors other than normal inter-test variability contributed to differences in thresholds observed with the two earphones. These data are being subjected to further analysis and studies to replicate these findings are planned with emphasis on the analysis of the differences based on acoustic immittance data and the type of middle ear pathology.

The effect of the residual volume of the ear canal on the dependent variables of ear canal spectrum produced by a hearing-aid-like earphone and upon pure-tone thresholds has been studied on 20 normally hearing subjects. The volume of the ear canal was manipulated by fabricating two sizes of earmold which were tightly coupled to the ear. The mean residual volumes resulting from the insertion of the long and short earmolds differed by 0.24 cc and resulted in ear canal sound pressure level (SPL) differences ranging from 0.4 to 3.6 dB at 500 and 3,000 Hz, respectively. The greater SPLs were associated with the smaller volumes. The threshold differences were smaller and the variability greater than with the spectral measures.

Future Plans—A follow-up study to assess whether the relationship between the above-mentioned dependent variables and ear canal volume is affected by venting the earmold has been initiated, and data collected on ten normally hearing subjects. The presence of the vent essentially eliminates the spectral and threshold differences attributable to volume.

Publications Resulting from This Research

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Direct Measurement of Loudness Recruitment in Hearing-Impaired Veterans

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C296-2RA)*

Purpose—The primary goal of this investigation is to further develop, test, and standardize a direct psychophysical scaling procedure for the measurement of loudness in sensorineural impairment.

Progress—Work this year has focused on three research areas. They are: 1) measurement of loudness at a frequency in the region of impaired hearing; 2) determination of the role of high-frequency hearing on the growth of loudness at low frequencies; and, 3) analysis and evaluation of audiograms from a population of 2,280 male participants in a normative aging study. Loudness measurements were obtained mainly by absolute magnitude estimation (AME), absolute magnitude production (AMP), and cross-modality matching (CMM) between loudness and perceived length.

Because the relation between loudness and sound intensity in sensorineural impairment is not a simple power function with a fixed slope, a second order least-squares fit was needed to describe the curvilinear shape of the loudness function in log-log coordinates. For this purpose, parabola fits to the individual sensation-magnitude data were generated from a computer program. Best-fitting power functions were then obtained to approximate the steep linear portion of the parabola. Using this approach, loudness exponents (slopes) determined directly from measurements of AME and AMP of loudness were compared to loudness exponents predicted from CMM and AME of perceived length. Typically, individual differences between the predicted and measured slopes were smaller for the parabola than for the simple power-function fit. To date, 76 people with sensorineural impairment have been tested at a frequency in the region of impaired hearing. From this group, 20 people with bilateral sloping high-frequency losses were also tested at 2 frequencies in the region of normal hearing. An assessment of the audiograms from the normative aging population is underway.

Preliminary Results—Results show that the measured and predicted values of the slope of loudness function are generally in agreement. For the whole group of 76 people, the mean value of the slope is 1.88 for the measured distribution and 1.84 for the predicted distribution. For a subpopulation of 57 people with noise-induced losses, the means of the measured and predicted distributions of slopes are 2.03 and 1.95, respectively. Thus, on the average, the measured deviation amounts to −2.0 percent, with more than half of the 76 measured deviations extending from −18.4 to 32.8 percent.

A similarly close agreement between the measured and predicted mean slopes, but with somewhat less intersubject variability, was reported in the *VA Rehabilitation R&D Progress Reports, 1987* for 51 people with normal hearing. However, for both the whole group and the subpopulation, the measured and predicted means are more than 3 times larger than the mean of 0.56 obtained in normal hearing. The results also show that the ranges and distributions of the predicted slopes for individuals clearly distinguish between the normal and impaired populations. The slope of only one person with normal hearing lies within the hearing-impaired range.

For the 20 people with steeply sloping losses, the lack of high-frequency hearing has only a small effect on the loudness of a tone at a frequency adjacent to the region of impaired hearing. This surprising finding provides added support for the notion that the output of the whole auditory nerve is unnecessary to cover the dynamic range of at least 100 dB observed for loudness.

Future Plans/Implications—The development phase of research is completed. The next phase of the study will focus on the effects of aging on the loudness function, and on the possible relation between the shape of the audiogram and the pattern of loudness growth. Suitable candidates from the normative aging study must be identified and tested.

Publications Resulting from This Research

On the Relation Between the Growth of Loudness and the Discrimination of Intensity for Pure Tones. Hellman R, Scharf B, Teghtsooian M, *J Acoust Soc Am* 82(2):448-453, 1987.

Measured and Calculated Loudness of Complex Sounds. Hellman R, Zwicker E, *Proceedings of Inter-Noise 87* 2:973-976, Beijing, China 1987.

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Why Can a Decrease in db(A) Produce an Increase in Loudness? Hellman R, Zwicker E, *J Acoust Soc Am* 82(5):1700-1705, 1987.

Prediction of Individual Loudness Exponents from Cross-Modality Matching. Hellman R, Meiselman C, *J Speech Hear Res* (in press).

Non-Linear Extension of the McGill-Goldberg Counting Model. Hellman W, Hellman R, *Proceedings of the International Neural Network Society* (in press).

Loudness Functions in Noise-Induced and Noise-Simulated Hearing Losses. Hellman R, *The 5th International Congress on Noise as a Public Health Problem*, Stockholm, Sweden (in press).

Perception of Reverberation by the Hearing Impaired

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C382-RA)*

Purpose—Reverberant environments act as acoustical filters whose frequency responses typically exhibit large numbers of ripples. These ripples are imposed upon the spectra of sounds that are generated within the reverberant environment, and appear as peaks and notches in the spectrum. Little study to date has been directed toward the perceptibility of such characteristics of the microstructure of reverberation, how these factors affect the perception of speech, or how reverberation may be modified by the smoothing of the reverberant spectrum. One objective of this study is to determine how spectral ripples generated by reverberation contribute to the perceptibility of reverberation.

Methodology—Two experiments address the relationship between the frequency of spectral ripples and their perceptibility. In one study, the stimuli consisted of: 1) one-second duration noise bursts, the spectra of which include a notch that is one-half of a critical band wide; or 2) one-second duration noise bursts, the spectra of which include a peak that is one-half of a critical band wide. The depths of the notches and heights of the peaks varied over a 12 dB range. The subjects' task was to distinguish between sounds with flat, versus peaked/troughed spectra, and between spectra having peaks (valleys) of differing amplitudes. The second study of this series involved sounds recorded in a room with a reverberation time approximating 400 msec. The test stimuli included a burst of white noise, as well as sustained productions of the vowels /i/, /a/, and /u/. These reverberated sounds were then subjected to a digital filtering paradigm which smooths the ripple in their reverberant spectra. The widths of the spectrum-smoothing filter conditions ranged from one-third critical band (to eliminate rapid, within-critical band ripples) to 11 critical bands (to eliminate long-period, between-critical band ripples). The subjects' task was to differentiate between the original reverberated, and the smoothed stimuli, using a two-alternative-forced-choice paradigm.

Results—Results to date for subjects with normal hearing are available for a number of the peak-valley experiments. These findings suggest that: 1) the spectral notches are not detectable, even when the depths of the notches are as large as 12 dB; and, 2) the minimum detectable amplitudes of the spectral peaks and the difference limen for spectral peaks approximates 3 dB.

Future Plans—Another phase of the project involves the recognition of reverberant speech as a function of differences in microstructure. A modification of the City University of New York Nonsense Syllable Test is being developed and standardized for this purpose. These materials are processed through the same room as mentioned above, using source and microphone locations that differ with respect to their proximity and orientation to the walls, as well as to the distances between them. These materials will also be subjected to the spectrum-smoothing conditions already described, the effects of which will be compared in terms of relative intelligibility. In particular, it will be determined whether differences in microstructure result in differences in perceived reverberant quality and in measured intelligibility; and whether smoothing results in changes in these measures. These conditions will be evaluated with and compared between normal and hearing-impaired listeners.

Measurement and Prediction of Benefit from Amplification

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C344-RA)*

Purpose—The objective of this project is to investigate the measurement and prediction of benefit received from hearing aid amplification in everyday life. The first 2-year period, which culminated during the past year, was devoted to the development of a test instrument to quantify the intelligibility of everyday speech—the Connected Speech Test (CST). During the next 3 years, scores on the CST will be used to study hearing aid benefit and to develop methods of predicting it.

Progress—Two investigations contributing to the development of the CST were completed. The first study was designed to provide the additional data necessary to determine critical differences and performance-intensity (P-I) function slope for hearing-impaired listeners. In the second study, normal hearers were used to assess the equivalence of the CST passage pairs when administered audiovisually.

Two new investigations are underway. The first involves the development of a self-administered questionnaire assessing hearing aid performance that will be used as a measure of hearing aid benefit. This instrument has been named the hearing aid performance profile (HAPP). One hundred initial items have been administered to 225 hearing aid wearers. The results have been subjected to factor analysis procedures to define areas of commonality. Data analysis is continuing. The second new investigation is a study of hearing aid benefit, quantified using CST scores, in 3 typical types of everyday environments. Interactions of benefit with visual cues, hearing aid response, environment type, and hearing loss, are of particular interest.

Results—The P-I function slope of the Connected Speech Test was found to be 8.5 rau/dB signal-to-babble ratio for hearing-impaired listeners. For pairs of scores, each based on mean performance across 2 randomly-chosen pairs of passages, the 95 percent critical difference was 15.5 rau. This work, along with other data for hearing-impaired subjects, is scheduled to appear in *Ear and Hearing*. Addition of the visual cues to the CST passages increased the variability of passage pair scores to some extent. To compensate for this, passages were grouped into equivalent sets of 4 or 6 passages. This new version of the test can be administered audiovisually or audio-only to normal or hearing-impaired listeners. This work has been submitted for publication.

Preliminary analysis of the HAPP data suggests that the profile will consist of 4 scales: communication in noise, communication in quiet, loudness of environmental sounds, and quality of environmental sounds. No results are available as yet in the study of hearing aid benefit in everyday environments.

Publications Resulting from This Research

Development of the Connected Speech Test (CST). Cox RM, Alexander GC, Gilmore C, *Ear Hear* 8(Suppl):119S-126S, 1987.

Composite Speech Spectrum for Hearing Aid Gain Prescriptions. Cox RM, Moore JN, *J Speech Hear Res*, 31:102-107, 1987.

Use of the Connected Speech Test (CST) with Hearing Impaired Listeners. Cox RM, Alexander GC, Gilmore C, Pusakulich, *Ear Hear* (in press).

Distribution of Short-Term RMS Levels in Conversational Speech. Cox RM, Matesich JS, Moore JN, *J Acoust Soc Am* (in press).

Studies on Amplification Selection for the Hearing-Impaired Veteran

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C307-RA)*

Purpose—The major purpose of this study is to evaluate the reliability and validity of three different hearing-aid selection procedures: the revised National Acoustics Laboratory (NAL-R) method, the Memphis State University method, and a modified version of the traditional Carhart comparative speech testing method. The data collected will also allow us to evaluate: 1) changes in user-satisfaction and measured performance over a one-year period following the hearing aid fitting; 2) the correspondence between laboratory measurements and the results of questionnaire data; 3) the correlation between behavioral thresholds, real-ear *in situ* responses, and the results of electroacoustic analysis in a 2 cc coupler; and, 4) factors which might influence ultimate user-satisfaction with a hearing aid, such as certain audiologic patterns, or the presence of other handicaps.

Methodology—One hundred subjects will be placed into each of the three selection protocols (a total of 300 subjects). Prior to the purchase of hearing aids, and at periodic intervals thereafter, each subject and a "significant other" will be administered a series of questionnaires including the Hearing Performance Inventory (HPI revised), the Hearing Handicap Inventory for the Elderly (HHIE short form), the Hearing Aid Performance Inventory (HAPI), and the Sickness Impact Profile (SIP). Screening will also be performed for other physical or mental handicaps.

Hearing aid fitting and evaluation will follow the protocol pertinent to the particular selection procedure. A FONIX 6500 real-ear measurement system will be used to verify the spectrum of the aided signal delivered to the eardrum. Once the hearing aids are adjusted to closely approximate the desired response, the Speech Perception in Noise (SPIN) test and the Nonsense Syllable Test (NST) will be used to indicate improvement in speech intelligibility. Behavioral measurements of functional gain will also be obtained.

Subjects will return at approximately 1 month, 6 months, and 1-year intervals after the hearing aid fitting for follow-up procedures. At these sessions, laboratory measurements will be re-obtained. A battery-exchange program will be conducted on about half of the subjects, and is designed to validate subjective reports regarding frequency of hearing aid use.

Progress—In the past year, there has been a change in the investigating team. Dr. Sammeth, who joined the faculty at Vanderbilt University in January 1988, has replaced the former co-principal investigator, Sid P. Bacon, PhD.

Some minor changes in the protocol have been agreed upon by the research team following consultation and further review of the relevant literature. In general, these changes involve the collection of additional data within a test session. For instance, two inventories (SIP and HHIE) and vision screening have been added to the original protocol. The NAL-R and COX selection procedures now reflect the newest versions published by their developers.

A computerized database has been established for ease in future statistical analysis of the data. Clinicians at both of the research sites are currently being familiarized with the protocol and methods.

Future Plans—Official implementation of data collection will begin within one month. Data collection will continue on a routine basis as eligible subjects pass through the hearing clinics, and the analysis of available data will be ongoing.

Development of a Digital Hearing Aid and Computer-Based Fitting Procedure: Phase II

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Purpose—The purpose of this research is to develop an all-digital hearing aid and a companion hearing assessment and hearing aid fitting procedure that will lead to improved performance of acoustic amplification for the hearing impaired.

Methodology—As has been described in earlier progress reports, a digital approach provides the flexibility of adjustment and control of auditory signal processing required to match the patient's hearing impairment. By incorporating the target hearing instrument into the hearing assessment and fitting procedure, variables such as the acoustics of the earmold and head can be directly accounted for in fitting the aid.

Work this year has been focused on: 1) evaluation of the digital hearing aid performance in psychoacoustic studies and field trials; 2) the development of processing algorithms; and, 3) development of a custom Very Large Scale Integrated (VLSI) circuit prototype that is intended as a precursor of the final production unit.

Results—The field study of the Wearable Digital Hearing Aid (WDHA) was started in the Fall of 1987, and the first subject, for whom extensive data was collected, was fitted in February 1988. Between February and the end of May, several changes were made in the test equipment, software for the real-ear gain measurement system, and in the fitting procedure. During this period, 13 subjects were fitted with the WDHA and wore it everyday for 3 weeks. Each kept a diary of volume control settings, comments on sound amplified with the WDHA and his or her own conventional hearing aid (CHA), and completed the Hearing Aid Performance Inventory before and after wearing the WDHA. In addition, 8 of these subjects took the Nonsense Syllable Test presented at 6 overall speech levels (45-80 dB SPL) in quiet and at 2 overall speech levels (45-80 dB SPL) in quiet and at 2 overall noise levels (Central Institute for the Deaf cafeteria noise at 42 and 57 dB Sound Pressure Level). Following this initial "shake down" period, 6 additional subjects were tested to evaluate the efficacy of the 4-channel model of the WDHA.

The results of the testing generally support the view that the more closely one can achieve a prescribed real-ear gain, the better will be the performance of the hearing aid.

Work has continued on the development of algorithms for feedback equalization, noise reduction, and signal compression. These algorithms are designed to accommodate dynamically changing conditions of signal and ambient noise, thereby extending the operating range of the digital hearing aid over what can be achieved by conventional means.

During 1988 we have continued our progress towards the ultimate goal of reducing the digital hearing aid to a VLSI chip set. The work has progressed in both the analog and digital subprojects. The chip, whose design was reported last year, has now been fabricated and tested and incorporated into a desk-top system which employs 4 of the digital signal processing chips to provide all 256 filter taps required for the 4-channel DSP system. A printed circuit board version of the analog-to-digital converter and digital-to-analog converter (ADC and DAC) circuit was completed, and used in conjunction with the 4-chip DSP to obtain a table-top, digital hearing aid system. The analog components were off-the-shelf commercial parts.

The design of the chip was improved further by an advanced multiplexing technique that enables the revised design chip to perform all 4 channels of digital signal processing on a single chip. It contains in excess of 50,000 transistors.

Future Plans/Implications—Numerous analog functional building block circuits have been designed and submitted for fabrication. These include several operational amplifiers, charge pumps, comparators, current and voltage references, and filters. We plan next to build a table-top system comprised solely of our custom circuits.

Basic Mechanisms and Rehabilitative Strategies for Presbycusis: Part I

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C251-2RA)*

Purpose—Over the past three years, we have determined the general auditory morphological and electrophysiological characteristics of the coturnix quail throughout its entire life span. This information is now being used as a basis for studying the influence of environmental and systemic toxins on the auditory system during the aging process. Specific questions are: 1) What is the anatomo/functional response pattern to acoustic trauma in the senescent auditory end organ? Is it similar to the response pattern seen in the developing end organ? 2) Is the potential for recovery from acoustic trauma different during the aging process? and, 3) What are the peripheral and central effects of gentamicin ototoxicity during aging?

Results—In the first experiments, young adult quail were exposed to an acoustically traumatic tone for 12 hours and allowed to survive from 0 to 60 days. The quail's inner ears were fixed, dissected free, embedded in plastic, and sectioned serially from base to apex at each survival interval. Ten days after trauma, the number of hair cells had decreased markedly; in the middle of the cochlea 70 percent of the hair cells were lost. Thirty days after trauma, hair cell loss was only 30 percent. A comparable experiment in senescent quail showed similar results. Thus the potential for anatomical recovery, at least at the hair cell level, does not differ as a function of aging.

In order to determine whether the recovery of cell number represented actual regeneration of new cells, a second set of experiments was performed. Adult quail were exposed to the same acoustic trauma as in the first experiment. Immediately after acoustic trauma, the birds received a series of injections of ^{3}H-thymidine. Autoradiography showed incorporation of ^{3}H-thymidine over hair cells and support cells in the area of hair cell loss. Control birds showed no incorporation of ^{3}H-thymidine. These results suggest that mitotic activity takes place after terminal mitosis in adult birds. This is the first evidence of hair cell regeneration after trauma in a warm-blooded vertebrate. It suggests that the potential may exist to restore inner ear sensory elements in other species after injury or disease.

Compound VIII nerve action potential thresholds have also been measured in young and old quail following acoustic trauma. A 30 to 40 dB hearing loss was found immediately following noise exposure. Within 24 hours, most of the functional hearing had returned. These results corroborate the anatomical findings above and confirm that aging has little effect on potential for recovery from acoustic trauma in quail.

In order to determine whether this potential for recovery might be generalized to other traumatic or toxic events, the ototoxic drug gentamicin was administered and the birds were followed over a period of 40 days. The initial response to gentamicin ototoxicity was a 30 percent reduction in hair cell number and a significant shrinkage in cochlear neuronal size. After 40 days, hair cell number and neuronal size had returned to nearly normal. These results confirm the capacity for hair cell recovery after trauma or toxicity.

Implications—These studies show that hair cells can regenerate after terminal mitosis in the inner ear of birds. In addition, they show that this regenerative potential is retained throughout the adult life. Although the location and mechanism of activation of the precursor cells responsible for mitotic activity are yet to be identified, the potential may exist to restore inner ear sensory elements after injury or disease.

Basic Mechanisms and Rehabilitative Strategies for Presbycusis: Part II

Purpose—Concurrent with the anatomical and electrophysiological studies in birds, we propose to explore the possibility of an altered preference for frequency response and/or gain characteristics of amplification in the elderly human hearing-impaired population. Specific questions are: 1) Is there an altered preference for frequency and/or gain characteristics of amplification devices in the elderly? and, 2) Do any particular formula approaches approximate these characteristics better than others?

Results—In our first set of experiments we have determined the actual use gain and frequency response characteristics of currently worn hearing aids in two populations: young (<65 years, mean age = 55) and old (>65 years, mean age = 79). These patients had various configurations of hearing loss, but had all worn hearing aids for at least two years, and reported that they were very satisfied with these instruments. Real ear insertion gain was measured, with the volume control of the hearing aid set to their normal use setting and using their own earmold, using a Rastronics CCI-10 probe microphone system. Normal use gain for frequencies from 250 Hz to 4,000 Hz was compared between old and young groups. Three formulae for predicting gain were also applied to the audiometric thresholds of each group in order to determine if the use gain for each group could be predicted by a formula approach.

In general, the younger group used slightly more gain, particularly in the lower frequencies. The greatest difference between the groups was in use gain at 500 Hz and 4,000 Hz. This was reflected in a greater low frequency slope and smaller high frequency slope in the older group. When the three formulae were applied, we found that all formulae over-predicted gain at 1,500 Hz and below in the older group and under-predicted gain at 1,500 Hz and below in the younger group.

Implications—The results of the current study are preliminary. The question still remains as to whether these were the optimal levels of amplification or simply levels which were in use and meeting the current needs of the subjects. Results suggest, however, that the low frequency amplifications needs of those over 65 years of age may be different from those under 65. Future studies will use a paired comparison matrix procedure to better determine optimal characteristics which may be preferred in various background noise, quiet, or reverberant conditions.

Publications Resulting from This Research

Hair Cell Regeneration after Acoustic Trauma in Adult Coturnix Quail. Ryals BM, Rubel EW, *Science* 240:1774, 1988.

Hair Cell Regeneration after Acoustic Trauma in Adult Coturnix Quail. Ryals BM, Westbrook EW, Rubel EW, *Assoc Res Otol* 11:34, 1988.

Recovery of Hair Cell Number in the Chick Basilar Papilla after Gentamicin Toxicity. Westbrook EW, Ryals BM, Lippe W, *Assoc Res Otol* 11:50, 1988.

Ganglion Cell and Hair Cell Loss in Coturnix Quail Associated with Aging. Ryals BM, Rubel EW, *Hear Res* (accepted for publication).

Visual Signals Project

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Sponsor: *Architectural and Transportation Barriers Compliance Board*

Purpose—The Visual Signals Project was sponsored by the U.S. Architectural and Transportation Barriers Compliance Board (ATBCB) to conduct human factors research on the characteristics of visual signals which might be used as emergency alarms for persons with hearing impairments. The research team consisted of Applied Concepts Corporation of Edinburg, VA, and its major subcontractor, the New York League for the Hard of Hearing. The purpose of the research was to consider modifications to the Minimum Guidelines and Requirements for Accessible Design (MGRAD) in light of the results of human factors testing. Results and recommendations were reported in *Visual Signals Project: Final Report.*

Results—The results of the Visual Signals Project provided a basis for defining a composite visual signal, and for defining the appropriate placement of such visual signaling appliances. The signal was named "composite" to distinguish it from "direct" and "indirect visible signaling appliances," which are the major types defined by the American National Standards Institute (ANSI) and the National Fire Protection Association (NFPA). Based on tests of over 200 subjects in 3 phases, visual signals with the following characteristics were found to be generally effective in alerting people with hearing impairments in a variety of office environments: 1) Type of light: xenon flash tube; 2) Color of light: white or clear; 3) Flash rate: 1 Hz to 3 Hz; 4) Intensity: minimum of 75 candela-seconds, maximum of 120; and, 5) Flash duration: approximately 1 ms.

The research team briefly considered portable pagers with a vibro-tactile output as an alternative to visual signals. For a variety of psychological, social, and institutional factors, the research team is skeptical about the practicalities of such a system for an infrequent use such as a life safety system.

A cost impact analysis was performed in order to estimate the cost of providing visual signals. Two typical office buildings were modeled to determine the relative costs of existing alarm systems and of different visual signal utilization options. A consideration of the level of coverage versus cost led the research team to recommend the use of visual signals in all restrooms and other general usage areas where an employee is likely to be alone at any time; in hallways, lobbies and other common-use areas, and in office and other individual use areas where a person with hearing impairments is an assigned occupant. This approach can be expected to raise alarm system costs by 8 to 50 percent depending on building design. This is a net impact of 0.06 to 0.12 percent of total building cost.

Signal Treatment for Improvement of the Effectiveness of Hearing Aids

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The objective of this project is the experimental evaluation of two concepts in the field of signal treatment, with the aim of improving the understandability of speech intensified by the hearing aid. Both concepts aim at the situation where the speech signal is interfered with by other sounds; this situation is most difficult for those who are hard of hearing.

These concepts represent two distinctive approaches: 1) the selective weakening of disturbing sounds on the basis of the angle of incidence; and, 2) the dynamic adaptation of the level of presentation to the threshold of audibility.

Progress—In consultation with the industries involved in the project, priority was given to concept two; concept one was not developed. The "philosophy" of concept two is that people who are hard of hearing often have a strongly-reduced dynamic range from their (heightened) threshold of audibility to the level of unpleasant loudness. It is therefore desirable to use this range optimally by intensifying the frequency-dependence of the speech signal, in such a way that all components are well above the threshold of audibility. As the acoustic circumstances of listening can continually vary, the frequency-dependent intensification should be adapted automatically by the incoming signal, which may lead, among other things, to selective weakening of low-frequency interfering signals (e.g., in a moving car or bus). This frequency-dependency can be achieved by dividing the frequency spectrum of the speech signal into 4 channels and by arranging for automatic adaptation by channel. The present level of technique (chip) makes it possible to fit the necessary circuit into the hearing aid. The industry has by now admitted that the concept can lead to important improvements of hearing aids.

This project was conducted in cooperation with T. Houtgast, TNO Department of Sense Physiology, 3769 ZG Soesterberg, The Netherlands.

Publications Resulting from This Research

The Effect of Varying the Slope of the Amplitude-Frequency Response on the Masked Speech-Reception Threshold of Sentences. Dijkhuizen van JN, Anema PC, Plomp R, *J Acoust Soc Am* 81:465-469, 1987.

Grafikom Project

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Grafikom is an aid which should enable deaf people to communicate and to be educated. This project investigated: 1) whether written communication with the use of Grafikom is a good means for learning a language; 2) what the application possibilities of Grafikom (evaluation of the apparatus) are; and, 3) what is the process of written language development in students who work with Grafikom equipment.

Progress—Data on the evaluation of the equipment are still being collected via journals kept by the teachers. Data about the written language development are still being collected via two monthly discussions between teacher and student. The conversations are being analyzed; the final processing of the analysis will be done by computer.

Results—It has become clear that written communication is not a good means for learning language because the communication is too slow.

Publications Resulting from This Research

Het Gebruik van Groepgrafische Apparatuur als Communicatiemiddel. Fortgens C, *Van Horen Zeggen*, Vol. 28, 1987.

Mini-Microphone to be Made of Silicon for Use in Hearing Aids

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is to produce an electret mini-microphone for use in hearing aids with the use of silicon technology. At the same time, it will be checked whether silicon oxide can be used as electret, because, for production, this is preferred over the conventionally-applied teflon folio.

Results—Prototypes of microphones with a teflon electret have been realized; they partly met the desired specifications for use in hearing aids. Furthermore, the research indicates that application of silicon oxide as electret is, in theory, possible, and even promises higher expectations. Also, it will be used in a follow-up project, because of the huge advantages to production.

This project was conducted in cooperation with the University of Twente and Microtel BV.

Development of a Portable, Programmable Sound Recognition Device to Promote Independence for Persons with Severe or Profound Hearing Impairments

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The objective of this project is to develop a new generation sensory aid to provide visual information on important environmental sounds. It is anticipated that the sound recognition device will be programmable by the user and will utilize the auditory signatures of sounds to accurately recognize and identify each sound. New information processing technologies make it possible to design sound recognition devices that provide more information at lower cost. More importantly, the devices can be made to be programmable, in order to respond to the specific sound cues that occur in a particular environment.

Progress—The first year of this project consisted of three tasks, namely, establishing user needs and preferences, establishing proof of concept, and developing a conceptual design. All three tasks have been completed.

Future Plans/Implications—The second year will consist of four tasks: preparing a detailed design, fabricating prototypes, conducting controlled environmental tests, and developing the final design. The third year will consist of three tasks, namely, fabricating prototypes, conducting field tests, and modifying the final design.

A practical sound recognition system will have to integrate three parts into an affordable package: a sensor (microphone), a processor/controller, and an output device. A sound recognition system is analogous to a voice recognition system, but simpler and less expensive. This research and development project will take advantage of recent advances in integrated circuitry to achieve a device which is flexible, simple to use, and inexpensive; thus, of maximum utility to the largest number of users.

The research team consists of Applied Concepts Corporation and Self Help for Hard of Hearing People, Inc. (SHHH). In addition, Dr. Judith Harkins, Director of Gallaudet Research Institute's Technology Assessment Program, is providing guidance and advice.

Cochlear Mechanics and Hair Cell Transduction

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Sponsor: *National Institutes of Health*

Progress—A mathematical model of cochlear processing accounts for the nonlinear dependence of frequency selectivity on intensity in inner hair cell and auditory nerve fiber responses. The model describes the transformation from acoustic stimuli to intracellular hair cell potentials in the cochlea. It incorporates a linear formulation of basilar membrane mechanics and subtectorial fluid-cilia displacement coupling, and a simplified description of the inner hair cell nonlinear transduction process. The analysis at this stage is restricted to relatively low frequency single tones. The computed responses to single tone inputs exhibit the experimentally-observed nonlinear effects of increasing intensity such as the increase in the bandwidth of frequency selectivity and the downward shift of the best frequency.

Preliminary Results—In the model, the first effect is primarily due to the saturating effect of hair cell nonlinearity. The second results from the combined effects of both the nonlinearity and the inner hair cell lowpass transfer function. In contrast to these shifts along the frequency axis, the model does not exhibit intensity dependent shifts of the spatial location along the cochlea of the peak response for a given single tone. The observed shifts, therefore, do not contradict an intensity-invariant tonotopic code.

Audiology ABR Analysis and Interpretation Expert System

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Sponsor: *National Institutes of Health*

Purpose—The objective of this continuing project has been to build an expert system to analyze and interpret the Auditory Brainstem Response (ABR), an electrophysiological response of the brainstem to acoustic stimuli. Expert reading of the ABR is essential in clinical decisions concerning retrocochlear disorders.

Hearing Assessment in Normal Volunteers

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Sponsor: *National Institutes of Health*

Purpose/Progress—During this fiscal year, the three-year review was accomplished and subsequent changes were made in professional staff. Approval was given for the continuance of the study in its revised form in early January 1987.

Since the last review, approximately 75 normal volunteers have been studied, thereby providing the necessary database for normal values in auditory-evoked potentials using circumaural headphones. Norms were developed for different stimulus rates, intensities, and polarities as well as for different age and sex groups. With the addition of new insert earphones and multi-frequency immittance equipment, we are looking forward to gathering normal values for these instruments and techniques as they will provide the necessary basis for comparison with the different age and disease populations studied in the Audiology Clinic as part of broader collaborative efforts.

During the few months in which the revised protocol has been in place, we have seen 6 normal subjects for the insert earphone study of brainstem and later-auditory-evoked potentials. Software modifications on our multi-frequency immittance equipment seem now to be current and should allow us to begin gathering norms.

Naturally, as the Audiology Clinic is officially a service organization, our patients' needs come first, and we see normal volunteers for this study only when no patient would be deprived of an audiologic assessment. However, age- and sex-matched normal controls are seen regularly as part of other collaborative protocols.

C. Speech Impairment

1. Hearing Related

An Auditory Prosthesis for Sensorineural Hearing Loss

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C054-3RA)*

Purpose—The object of this research is to determine the optimal design parameters and fitting procedures for a new multichannel compression hearing aid for patients with sensorineural hearing loss (SNHL). Previously, we have demonstrated that an initial 8-channel version of the aid was very effective in helping individuals with SNHL to recognize speech sounds in the presence of noise—a key problem for SNHL patients. The present work will include a systematic study of the following parameters of the multichannel compression hearing aid: 1) number of channels; 2) time constant of the compression; 3) location of the channel boundaries with respect to the configuration of the hearing loss; 4) type of compression system; and, 5) shape of the compression function. The present work will also examine the importance of learning to use a multichannel compression hearing aid. Aspects of the previous results suggested that the performance of the subjects with the new aid had continued to improve throughout the study (over 40 hours of testing per subject).

Progress—The effect of the number of channels in the multichannel compression aid has now been measured in 15 SNHL subjects at 5 signal-to-noise ratios (S/N) with both a male and female voice. Otherwise, equivalent multichannel compression processing with 4, 6, 8, 12, and 16 channels was tested. At this time, we have begun to measure the effect of varying the time constant of the compression.

Preliminary Results—Averaged across all S/N used (−5, 0, 5, 10, and 15), the performance of the multichannel compression system tended to improve as the number of channels increased, although the improvement between 4 and 8 channels was much greater than that between 8 and 16 channels. Individually, no subjects achieved the best performance with 4 channels, and only one achieved the best performance with 6 channels; in many subjects, the difference between 8, 12 and 16 channels was not statistically significant. More channels also tended to be relatively better at lower S/N than at higher S/N, but a more complete analysis of the data remains to be done. Some of the differences across subjects may be due to the positions of the channel boundaries with respect to their hearing loss configurations—an effect to be studied in detail later.

Publications Resulting from This Research

Speech Perception with an Eight-Channel Compression Hearing Aid and Conventional Aids in a Background of Speech-Band Noise. Yund EW, Simon HJ, Efron R, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:401-403, 1987.

Speech Discrimination with an 8-Channel Compression Hearing Aid and Conventional Aids in a Background of Speech-Band Noise. Yund EW, Simon HJ, Efron R, *J Rehabil Res Dev* 24(4):161-180, 1987.

C. Speech Impairment

2. Aphasia

Hierarchical Computerized Language Treatment for Aphasic Adults

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C400-RA)*

Purpose—Recent reports imply that microcomputers may be effective in providing language treatment for aphasic adults. This current project is based on earlier work by the investigators, and it expands the use of complex algorithms and hierarchically-arranged tasks to deliver language treatment appropriate for each patient's level of severity. The purpose of the study is to develop hierarchically-arranged reading and writing treatment software, and test its effectiveness by comparing improvement in patients who receive computerized language treatment with that of patients who receive computer-stimulation ("non-language" activities) or no treatment.

Progress—Equipment and non-treatment software have been ordered and received at the two development sites. Non-treatment computer software has been selected and organized for the computer-stimulation group. A *Comprehensive Communication Assessment Test* (CCAT) has been developed and written. Reading-treatment software has been written, coded, and tested. Writing software has been written and is currently being coded. Study patients are being recruited, evaluated, and assigned randomly to the three conditions: computer language treatment, computer-stimulation, and no treatment.

Preliminary Results—Patients in the computer language treatment and computer-stimulation groups are performing well and moving through the computer activities quickly. Pilot testing on some writing programs indicated that aphasic patients learned the tasks, and improved performance transferred to related, cursive writing tasks.

Future Plans/Implications—The coding of writing-treatment software will be completed shortly. Additional patients are being recruited and assigned randomly to the three groups. The results of the investigation should demonstrate whether computerized language treatment for chronic aphasia is effective, and whether this type of treatment can be administered by a computer with minimal assistance from a clinician.

Publications Resulting from This Research

A Computer Program to Improve Written Confrontation Naming in Aphasia. Katz RC, Wertz RT, Davidoff M, Shubitowski YD, Devitt EW, in *Proceedings of 1988 Conference on Clinical Aphasiology*, Minneapolis: BRK Publishers (in press).

Microcomputer Applications in Research on Treatment of Aphasia. Katz RC, in *Communication Sciences and Disorders and Aging: Conference Proceedings*, Rockville: American Speech-Language-Hearing Association (in press).

Computer-Aided Visual Communication for Severely Impaired Aphasics

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C292-RA)*

Purpose—The purpose of this project is to develop a visually-oriented, computer-based alternative communication system which can be used to improve communicative function in the most severely-impaired, chronically aphasic individuals. The goal is to develop a system which runs on a compact and affordable computer—the Apple Macintosh—and which is operable by patients and useful to them in daily life. As this Computer-assisted Visual Communication (C-VIC) system is being developed, we are teaching patients how to operate the interface in accessing individual pictographs, how to use the pictographs in building meaningful communications, and how to employ their productions communicatively.

Progress—We have completed Version 1.0 of the C-VIC program, which largely represents a computerized version of earlier flashcard-based work. Studies with this version of the system demonstrate that subjects: 1) are able to learn and negotiate the complex, hierarchically-organized, window-based computer interface which the new medium presents; 2) can perform in the new medium at a level far superior to their performance in natural English; 3) benefit from the ability of the computer to reduce both motoric and organizational demands made on the subjects; 4) can operate with vocabularies of up to 250 individual items organized heirarchically on semantic bases; and, 5) demonstrate marked enthusiasm for work on the system. The work has also revealed the weaker points in subjects' performance: 1) patients' performance with verbs is uncertain and may be incorrect; 2) certain categories [e.g., prepositions] may be learned adequately in the clinic, but are infrequently used spontaneously; and, 3) patients' expressive performance is, in general, weaker than their receptive performance.

We are now engaged in the research and development of C-VIC Version 2.0, which aims to utilize the strengths of the computer medium to help address those areas of patient difficulty revealed in our earlier work. Among other things, this second version of the interface allows us to construct visual communications in advance and summon them up later as templates during training or actual use. It allows for items to be animated, which can be useful in improving performance with verbs. Additionally, we are looking towards the incorporation of targeted artificial intelligence (AI) capabilities, which will allow the computer to interpret sequences of actions within certain structured contexts (e.g., taking a meal in a restaurant), make deductions, and use the conclusions to provide the user with cues to help improve performance.

Results—Overall, our clinical studies suggest that the C-VIC system may hold rehabilitation potential for four different applications. 1) As a *dialog facilitator,* the system has already demonstrated its utility. In this application, C-VIC visual communications are constructed as an adjunct to support spoken communication wherever possible, and in this combined modality, patients perform at their best. 2) The system has demonstrated its utility as an *aid to support complex task performance.* In exercises requiring aphasic patients to prepare several recipes, subjects performed consistently at a functional level when instructions were presented in visual communications. 3) The C-VIC system may also support *intersystemic reorganization* in some aphasic patients, which idea awaits further investigation. 4) The system appears to hold promise as an *early therapeutic intervention,* and studies by colleagues elsewhere have just begun to evaluate its potential in this application.

Future Plans/Implications—Patients have demonstrated their affinity for the system and their ability to master important components of the system. This suggests that future work will need to draw on the power of the processor to help support accurate and reliable patient performance in the representation of individual lexical items, in the use of syntax to combine individual symbols into complex communications, and in the development of AI modules which will support functional performance in selected complex, but conventionally-structured, contexts of human activities.

Publications Resulting from This Research

Evaluating Performance of Severely Aphasic Patients on a Computer-Aid Visual Communication System. Steele RD, Weinrich M, Kleczewska MK, Carlson GS, Wertz R, *Clinical Aphasiology 1987,* Minneapolis: BRK Publishers, 1987.

Targeted Applications for Aphasia Rehabilitation: Computer Aided Visual Communication in Aphasia. Steele RD, Weinrich M, Kleczewska MK, Carlson GS, Hennies D, in *Proceedings of the ICAART Conference,* 48-49, Montreal, 1988.

Prospects for Aphasia Rehabilitation. Weinrich M, Steele RD, in *Proceedings of the ICAART Conference,* 560-563, Montreal, 1988.

Computer-Based Visual Communication in Aphasia. Steele RD, Weinrich M, Wertz R, Kleczewska MK, Carlson GS, *Neuropsychologia* (in press).

Processing of Visual Syntax in a Globally Aphasic Patient. Weinrich M, Steele RD, Carlson GS, Kleczewska MK, Wertz R, Baker E, *Brain and Language* (in press).

Representation of "Verbs" in a Non-Verbal Visual Communication System. Weinrich M, Steele RD, Kleczewska MK, Carlson GS, Baker E, *Aphasiology* (in press).

The Application of Microcomputers for the Treatment of Aphasic Adults

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Purpose—The use of microcomputers in the rehabilitation of brain damaged patients continues to win popularity in some clinical settings. Cost effectiveness, operational efficiency, and increased treatment-time allocations without additional human resources are the high tech features that bolster their acceptance and application. Yet database research in speech/language pathology concerning treatment efficacy remains sparse. The field presently lacks convincing data as to the efficacy of using microcomputers for the rehabilitation of aphasic adults. The purpose of the present study is to answer the following question: are microcomputers more effective in teaching a criterion performance than the same procedure presented by a clinician?

Progress—The study is being made up of 20 chronic aphasic patients who have sustained a single lesion to the left hemisphere. Each aphasic person within this study population will be in the mild-to-moderate range of aphasic severity. To study treatment effectiveness, an alternating treatment design with multiple probes (single case), is utilized. By using this type of design, baseline performance, the effects of treatment, maintenance of behavior, and generalization across treatment, tasks can easily be viewed. All patients receive two modes of treatment (clinician and microcomputer) daily, in a rapidly alternating fashion.

The microcomputer and clinician treatment packages are identical in terms of types of stimuli, modality, and randomization of presentation, type of feedback, and scoring. The treatment itself is a well-established protocol which has been demonstrated to be effective with this population of patients.

Preliminary Results—Twenty patients/subjects have entered into the study and have completed the treatment package. Aphasic patients as a group require approximately 28 percent more visits to reach overall treatment criteria with the microcomputer-clinician assisted treatment than with the clinician alone. When these data were examined by type of aphasia, a significant difference ($p<0.05$) in number of visits to reach criteria merge. The fluent group required 24 percent more visits via the computer-clinician assisted treatment than with the clinician alone. The non-fluent subjects needed 33 percent more with the computer assisted treatment versus the clinician alone. It has also been established that overall treatment levels 1 and 2 required significantly ($p<0.05$) more sessions to reach criteria than treatment levels 1a, 1b, or 2a. The major differences in performance between modes of treatment occurred on treatment levels 1b and 2b. Examination of these data by various severity levels of aphasia yielded no significant differences.

Besides treatment-specific data, this research also explored the impact of this program on overall language function as measured by the Porch Index of Communicative Ability (PICA). Interpretation of external PICA probes for each patient indicated that 14 of 18 patients showed significant improvement on the PICA overall measure from baseline to maintenance probes with the most significant increases occurring after treatment level 1. Fifteen of 18 patients showed significant improvement across the verbal modality measure and 16 of 18 patients across the graphic modality measure. All patients maintain these gains after maintenance phase of no less than one month post-treatment.

In summary, the present research demonstrates that this treatment program is an effective tool for aphasic adults. It further replicates previous research and establishes a database regarding the microcomputer-clinician assisted medium as a primary treatment delivery system. It appears that the use of microcomputers in the clinical setting should be approached with caution. The present investigation demonstrates the clinician was generally more efficient than the microcomputer-clinician assisted for both fluent and non-fluent aphasic adults above the 50th percentile on the PICA.

Future Plans/Implications—Research needs to continue measuring the effects of this program with more subjects, more types of aphasia, and more severity levels of this disorder for both clinician and computer modes of treatment. Additionally, cueing hierarchies for eliciting the actor-action-object framework needs to be explored further along this task continuum. This would enable the patient to receive the most efficacious cueing stimuli to maximize his/her output. Additionally, changing the order of presentation of the 6-tier treatment hierarchy could be beneficial for certain types and severities of aphasia. The future efforts should make available a reliable, effective treatment program for both the microcomputer and clinician modes of treatment in the rehabilitation of aphasic adults to other facilities with similar case loads.

Publications Resulting from This Research

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Cueing Verbs: A Treatment Strategy for Aphasic Adults (CVT). Loverso FL, Prescott TE, Selinger M, *J Rehabil Res Dev*, 25(2):47-60, 1988.

Comparison of Two Modes of Aphasia Treatment: Clinician and Computer. Loverso FL, Prescott TE, Riley L, Selinger M, in *Clinical Aphasiology*, San Diego: College Hill Press (in press).

The Development of Microcomputer and Clinician Treatment Procedures for Aphasia (Project Extension)

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Purpose—The purpose of the proposed research is to answer the following questions: 1) Are clinician-assisted microcomputer treatment programs as efficacious in treating marked aphasic individuals as they are compared to treating moderate-to-mild aphasic individuals? 2) Is a linguistic cueing hierarchy different for various types and levels of aphasic persons? 3) Can streamlining the treatment package by eliminating and/or rearranging hierarchical levels be beneficial to overall language recovery in aphasic individuals ranging in severity and type?

The first objective of this investigation is to provide 21 aphasic adults of various severity levels an opportunity to achieve significant increases in the level of their communicative functioning, using a well-established reliable treatment procedure. Objective two is to establish the most effective linguistic cueing treatment hierarchies for various types and levels of aphasia in two treatment mediums; microcomputer/clinician-assisted treatment, and clinician-alone treatment. The third objective is to determine whether or not streamlining the treatment package can be efficacious to overall language recovery of aphasia by eliminating and/or rearranging treatment levels.

This research will require each patient to receive treatment via the microcomputer, and the more traditional clinician-presented treatment on the same day, at a minimum of three times weekly. Time of day for each mode of treatment and type of treatment will be counterbalanced. The fourth objective is to make new reliable and efficacious treatment protocols available to other facilities with similar patient populations. The fifth and final objective is to create a training tape whereby clinicians could better understand and apply this developed treatment protocol effectively and efficiently.

The Influence of Mode of Stimulation on Naming Performance in Aphasia: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #C943-PA)*

Purpose—The purpose of this investigation is to examine the influence of situational context on the naming of noun and verb stimuli using realistic, videotaped stimuli. The design of the study will allow for comparison with previous studies using line drawings to determine if the number and type of errors produced by aphasic patients varies according to the mode of stimulus presentation. This will provide important information for speech-language pathologists who are routinely involved in the diagnosis and treatment of aphasia.

Progress—Currently, 33 aphasic patients have been included in the investigation, including 7 Broca's, 8 conduction, 8 Wernicke's, and 10 anomic aphasics.

Future Plans—It is hoped that by the conclusion of the study, 10 patients will be included in each aphasia syndrome. Following completion of the investigation, we will perform a number of statistical analyses of the data.

An Experimental Analysis of Response Elaboration Training in Aphasia

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Purpose—The primary purpose of this project is to examine the effectiveness and generality of Response Elaboration Training (RET) for aphasia. This procedure is a form of divergent semantic language intervention designed to facilitate an increase in the quantity and variety of verbal responses produced by patients with nonfluent aphasia. The emphasis in RET is on facilitating an increase in the amount of information contained in patients' verbalizations. Unlike more didactic training programs, specific lexical items are not targeted for intervention during RET. Rather, spontaneous, patient-initiated utterances are systematically chained together to elicit more elaborate verbal responding.

Methodology—A multiple baseline across behaviors and subjects design was used to explore two key questions: 1) Will RET facilitate an increase in the amount of information (number of content words) produced by aphasic subjects within the treatment setting? and, 2) Will RET result in generalization of more elaborate responding to untrained stimuli, settings, and individuals?

Progress—To date, seven aphasic subjects have completed the training protocol, and social validation data have been collected on ten age-matched normal subjects. Results to date indicate that RET facilitated an increase in the number of content words produced in response to training and generalization stimuli. Generalization of training effects to spontaneous interactions, novel settings, and individuals, although somewhat variable, was also found. The generality of RET was further explored by using the procedure with a nonverbal aphasic-apraxic patient in an attempt to train him to communicate through drawing. This cross-modality replication was successful. The patient developed an elaborate nonverbal (drawing) communication system on structured tasks and generalization occurred to untrained stimuli, settings, and people. Additional data are being collected and analyzed to evaluate changes in response efficiency that may occur following RET. In addition, efforts are currently underway to compare RET's "loose training" approach to more traditional, structured didactic treatment.

Publications Resulting from This Research

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Motor Speech Disorders: The Dysarthrias and Apraxia of Speech. Kearns KP, Simmons NN, *Handbook of Speech-Language Pathology and Audiology*, N.J. Lass, L.V. McReynolds, J. Northern, D. Yoder (Eds.), Lewiston, NY : B.C. Decker, Inc., 1988.

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Promoting Generalized Language Use: An Analysis of Treatment Strategies

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C330-RA)*

Purpose—The objective of our research program is to promote functional language use in adults with acquired language disorders. Treatment programs designed specifically to enhance generalization of verbal language behaviors to natural contexts have been developed and evaluated using single-case experimental research designs and social validation procedures.

Progress—One study employed a multiple baseline design across behaviors and subjects to evaluate the effects of a "loose" training procedure on the requesting behavior of 4 subjects with chronic Bronca's aphasia. Generalization across three conversational topics, persons, and settings was assessed in weekly probe sessions consisting of conversational interactions with familiar and unfamiliar conversational participants in a nontreatment setting. Results revealed marked generalization effects for all subjects to both familiar and unfamiliar conversational participants. Social validation procedures in which judges were naive to both the subjects and purpose of the study, revealed that subjects were rated as being significantly more talkative and inquisitive and the conversations were significantly more successful following treatment.

In another study, a multiple baseline design across behaviors and subjects was used to evaluate the effects of programming a common stimulus on language-impaired, demented subjects' ability to provide statements of fact in conversations with the experimenter and with familiar conversational partners. Subjects' spouses were taught to implement a twice-daily training program in the home in which subjects used a memory/communication wallet consisting of 10 picture-and-sentence stimuli for each of 3 conversational topics in order to prompt appropriate on-topic statements of fact. All subjects demonstrated consistently strong treatment and generalization effects which maintained throughout treatment of other topics and at 3- and 6-week follow-up sessions. Naive judges detected significant differences between baseline and post-treatment performance on 8 different conversational dimensions, socially validating the experimental effects.

A third study employed a multiple baseline design across behaviors and subjects to evaluate the effects of a combined deblocking/time-delay procedure on severely comprehension-impaired aphasic subjects' ability to learn single element verb-noun combinations. Subjects were trained to follow verb-noun intra-matrix generalization, and extra-matrix generalization effects were measured continuously over time. At the time of this report, 2 subjects have completed the protocol

Results—For Subject 1, generalization effects were robust, but were not rapidly forthcoming. Subject 2 learned a number of directly trained verb-noun directions, but generalization effects were not observed. We are currently recruiting additional subjects to participate in this study.

Future Plans/Implications—Future investigations planned include: 1) systematic replications of the effects of the loose training procedure across additional verbal behaviors; and, 2) an investigation of the effects of incidental teaching on establishing a core, functional verbal vocabulary in aphasics with severe verbal production deficits.

Rehabilitation of Neurogenic Communication Disorders in Remote Settings

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Purpose—We have simulated the use of video, computer, and telephonic technology to provide accurate appraisal, diagnosis, and treatment for patients who suffer neurogenic communication disorders and reside in remote settings. The purpose of this project is to determine whether an existing treatment center can provide appropriate and efficacious management to patients in remote settings by closed circuit television or computer controlled video laserdisc over the telephone.

Methodology—Patients who suffer neurogenic communication disorders are appraised and diagnosed in 3 conditions: traditional face-to-face, closed circuit television, and computer-controlled video laserdisc over the telephone. In addition, patients who suffer aphasia are assigned randomly to the 3 conditions for a 6-month treatment trial. Performance among conditions is compared to determine whether television and video laserdisc over the telephone provide essentially the same accuracy in appraisal and diagnosis and the same efficacy in treatment as traditional face-to-face appraisal, diagnosis, and treatment.

Results—Over 100 patients have been appraised and diagnosed in the simulation study, and 17 aphasic patients have been entered in the treatment trial. Analysis of 72 patients in the appraisal and diagnosis study indicates no significant differences ($p<0.05$) in the accuracy of appraisal and diagnosis among conditions. Thus, television or video laserdisc over the telephone appear to be acceptable alternatives to traditional face-to-face appraisal and diagnosis for patients who reside in remote settings. While the sample size is still too small in the treatment study to permit valid statistical comparison, patients in all conditions improve, and there is no apparent difference in improvement among conditions.

Future Plans—Presently, we are conducting a field test of the equipment and methods developed in the simulation study. Because there is a significant difference in the cost of television, approximately $200,000 in each remote setting, and video laserdisc over the telephone, approximately $15,000 in each setting, the field test compares appraisal, diagnosis, and treatment by video laserdisc over the telephone with traditional face-to-face management. Video laserdisc over the telephone is being provided in two outpatient clinics where services do not exist by clinicians, in the VA Medical Center, Martinez, Audiology and Speech Pathology Service. The field test is designed to continue until 1992 and should demonstrate whether an existing treatment center can provide accurate appraisal, diagnosis, and treatment by computer-controlled video laserdisc over the telephone to patients who reside where traditional services are not available.

Publications Resulting from This Research

Appraisal and Diagnosis of Neurogenic Communication Disorders in Remote Settings. Wertz RT, Dronkers NF, Bernstein-Ellis EG, Shubitowski Y, Elman R, Shenaut GK, Knight RT, Deal JL, *Clinical Aphasiology Conference Proceedings*, 117-123. Minneapolis: BRK Publishers, 1987.

Appraisal and Diagnosis of Neurogenic Communication Disorders in Remote Settings. Wertz RT, Dronkers NF, Bernstein-Ellis EG, Shubitowski Y, Elman R, Shenaut GK, Knight RT, Deal JL, *ASHA* 29:79-80, 1987.

System for Training Aphasia Patients

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—In 1981 a study into the possibilities of a computer-controlled practice program for treating aphasia patients was started. Speech therapists felt the need for an apparatus that could offer pictures, letters, words, and sentences, wherein a patient could influence continuation with a push-button, and thus be able to monitor his own performance (e.g., the writing of words) and ask for help. If the patient was unable to write the word, every push of the button would give another letter of the word. Thus, the System for Training of Aphasia Patients (STAP) was developed, aimed at offering aphasic patients the possibility of practicing by themselves.

Results—In the last few years, a number of prototypes for the STAP program have been developed. At first, an Apple microcomputer was used. However, after a field evaluation with 47 patients, the STAP program was transferred to an IBM-PC, because the extensions needed could not be realized on an Apple. Subsequently, a pilot study was conducted with 10 patients at home. The results of both investigations are incorporated in the current cluster program. The cluster program of STAP was sold to the Foundation Bergschot Centre for Research (BCR) in Breda. BCR will introduce the STAP program in phases, starting in mid-September 1988.

This program was conducted in cooperation with the Rehabilitation Centre DeHoogstraat, Leersum.

Publications Resulting from This Research

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The Use of Microcomputers in Diagnosis and Rehabilitation of Adult Aphasic Individuals

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Purpose—This project involves a series of studies to investigate the feasibility of using microcomputers in the diagnosis and treatment of adult aphasic individuals. The first study compared the performance of aphasic subjects on a computerized and on the standard version of the Colored Progressive Matrices (CPM), a visual, nonverbal problem-solving task. The second study examined the relative efficiency with which aphasic adults use different computer input systems (i.e., keyboard, long-range light pen, stylus, touch-sensitive screen, and joystick); performance on a measure of reading comprehension was compared across all interface systems. Results of this work will assist in the selection of appropriate input systems for aphasic users. Further, analysis of response characteristics using each of the interface systems will address the theoretical question of competition for cognitive resources: i.e., the degree of cognitive ability required of aphasic users to both operate the device and proceed with the test.

Another study in the series will investigate computer strategies for recognizing perseveration and self-correction attempts and will develop software to both interrupt perseveration and facilitate self-correction tendencies. The behavioral tool for this study is a computerized version of the Revised Token Test (McNeil and Prescott, 1978), a measure of auditory comprehension on which aphasic subjects are likely to display perseveration or self-correction tendencies.

Progress—*Study 1.* Comparisons of performance on the standard and computerized version of the CPM has shown that quality of performance in terms of percentage correct and response time does not vary significantly across test versions for our samples of severely, moderately, and mildly impaired subjects.

Study 2. The reading measure for this project is a multiple choice synonym identification test, with two levels of difficulty. A different test was developed for each interface system; all tests were designed to be equivalent in grade level. Algorithms for scoring and response-time data collection were devised. A Latin Square (complex) design was used for the study. Eleven subjects have been tested.

Study 3. The software routine developed for the Revised Token Test has been completed, including token movement, scoring, data collection, and speech generation algorithms. Programming algorithms for perseveration interruption and self-correction facilitation are being completed. Preliminary testing of software with 10 normal subjects has been completed and revisions are being made.

Future Plans—For Study 3, a series of single subjects design studies, using a multiple treatments design is planned.

C. Speech Impairment

3. Other

Effects of Real-Time Biofeedback on Dysarthric Speech

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C313-2RA)*

Purpose—This research program is devoted to developing and testing the effectiveness of computer controlled visual biofeedback in inducing changes in speech breathing and speech rate in normal and dysarthric subjects. Of particular interest are changes in speech intelligibility that may occur with changes in speech rate and speech breathing patterns. Cerebellar ataxic and Parkinson subjects are being studied and compared with normal control subjects.

Progress—We have developed an algorithm which provides a real-time metric highly correlated with speech rate and have applied this technique to both normal and disordered subjects.

Results—Our results thus far suggest that this technique can rapidly induce changes in speech rate for both normal and disordered subjects. The findings further suggest that altering speech rate does not adversely affect language parameters and does improve intelligibility in some subjects.

Future Plans—Additional work will focus on expanding computer acquisition of speech parameters and developing expert systems for interpretation of speech symptom profiles.

Computer-Assisted Speech Evaluation Expert System

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C468-RA)*

Purpose—This research program is devoted to developing and testing specific computer and instrumental procedures designed to measure aspects of speech and speech-related function in subjects with disordered speech. Software is being developed to extract and analyze speech acoustic, aerodynamic, and physiologic data during connected speech and specific diagnostic maneuvers.

The initial focus is on development and validation of the acquisition and analysis procedures that will result in objective measures of speech function. Additional work will relate these measures to human perceptual judgment. Finally, an expert system will be developed to assist in interpretation of obtained speech symptoms and to recommend additional diagnostic procedures as appropriate.

Acoustic Vowel Measures Following Radiation Therapy to the Larynx

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C336-RA)*

Purpose—Patients who have undergone radiation therapy for laryngeal carcinoma confined to a true vocal fold(s), in the absence of positive neck nodes or metastases, are often referred for voice therapy because of a residual hoarse voice. Clinically, it is known that hoarseness diminishes over time, following the completion of radiation therapy. The course and degree of voice change during and following radiation therapy, however, have not been thoroughly documented. Having such knowledge could greatly influence the decision-making process regarding the evaluation, management, and dismissal of patients having completed radiation therapy, and who subsequently are being considered for voice treatment. The objective of this study is to provide quantifiable acoustic data that are correlatively associated with voices produced by patients presenting such laryngeal carcinoma.

Methodology—Twenty patients meeting the above criteria and 20 normals will be entered into the study. Acoustic measures along with auditory and visual judgments will be collected prior to, during, and at 1-month intervals for one year following completion of radiation therapy.

Each patient will sustain five test vowels at a comfortable pitch and loudness for a minimum of 5 seconds for each vowel. All vowel samples will be acoustically analyzed to obtain spectral noise levels and correlated to auditory and visual measures.

Progress—Five patients have been entered into the study. Two died and one had to have a total laryngectomy. The project was recently moved to the VA Medical Center in Kansas City, MO, and will continue uninterrupted.

A Pilot Study on the Efficacy of Injected Cross-Linked Collagen in the Treatment of Symptomatic Glottic Insufficiency

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #A900-PA)*

Purpose—This pilot study was designed to determine the efficacy of injectable collagen in the aged larynx. Presbylaryngis is a term used to describe the laryngeal changes that occur as a function of aging. Among the changes that have been described are morphologic change such as connective tissue breakdown with disorganization of collagen fibers, loss of elastic fibers, ossification of laryngeal cartilages, muscle atrophy, and thickening of edema of the vocal folds. Associated with these morphologic changes are voice changes, including raised or lowered pitch, breathiness, roughness, and weakness. Presbylaryngis can be identified through the following acoustic and aerodynamic characteristics: reduced vocal range, reduced ability to sustain phonation, increased jitter and shimmer, and decreased signal to noise ratio.

Although presbylaryngis appears to be common among the elderly, there is little information about treating the voice problems associated with it. The purpose of this study was to investigate the effectiveness of injectable bovine collagen in augmenting bowed atrophic vocal folds of elderly patients with glottic insufficiency. We hypothesized that improvement in glottal closure would result in decreased airflow, increased intensity, and improved vocal quality.

Methodology—The effects of treatment were evaluated through a set of perceptual and objective measurements. The perceptual measurements were obtained by having independent judges rate audio recordings of subjects' voices along 5 parameters. Objective measurements of laryngeal function included acoustic, aerodynamic, and movement parameters. Studies of vocal function were conducted twice prior to treatment and at specified intervals following the injection.

Results—Of the 36 patients screened, 18 had presbylaryngis. Eleven patients were treated and followed over the requisite time to gather preliminary data. There were no adverse reactions to the collagen, and no patients felt that there was a decrement in the quality of their voice following treatment. Results varied, but video ostroboscopic studies tended to correlate well with the subjective responses of the patients, demonstrating improved glottic closure when vocal quality was found to be improved.

Implications—Results were difficult to interpret because of the wide range of variability exhibited by the subjects. Variability between the two "no treatment" test conditions was frequently as great or greater than any change resulting from treatment. Since no data exist on the variability of measures of vocal function for the elderly, it was difficult to discern whether collagen injections are an appropriate form of treatment in this population. The fact that very little change resulted from treatment could be interpreted to mean that increased glottal closure alone is insufficient to make the necessary changes to significantly improve voice. Another possible interpretation of these data is that it is necessary to determine the variability of measures of vocal function in this population before any conclusions can be drawn.

Publications Resulting from This Research

Observations on the Pathophysiology of Voice Disorders. Ford CN, Bless DM, Pratt S, American Laryngological Association Meeting, Palm Beach, CA, 1988. *Annals of Otology, Rhinology, and Laryngology: Transactions of the American Laryngological Association* (in press).

Voice Assessment of Patients Undergoing Surgery to Alter Pitch. Ford CN, Bless DM, Pratt S, Voice Symposium, New York, NY 1988. *Voice* (in press).

Bovine Collagen Injections in the Senile Larynx. Ford CN, Bless DM, Pratt S, presented at The American Speech, Language, and Hearing Association Meeting, Boston, MA, 1988.

Development and Evaluation of an Expert System to Facilitate Efficient Matching of Disabled People to Communication Devices

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The process of matching a disabled individual to the available communication devices requires evaluation of the client's capabilities and needs, followed by selection of a communication device from the range available. This process requires a skilled clinician with the appropriate expert knowledge. No state in Australia has a complete range of communication devices available for assessing clients. Therapists need to make a best guess from product literature and then purchase or borrow the device and trial it with the client. Our aim is to produce a system which will reliably pinpoint a communication device or range of devices which are most appropriate to the needs and abilities of individual clients. The system is aimed at assisting therapists in any location where a full range of communication devices is not available. This project will provide a valuable tool for existing expert clinicians, and will make this knowledge available to more clinicians.

Our specific aims are: 1) to develop a formalized selection procedure to facilitate efficient matching of people with disabilities to communication devices; 2) to embody this selection procedure into a computer system so as to make the procedure available to other workers who do not have the required expert knowledge; and, 3) to evaluate the selection procedure by testing its effectiveness when used by a number of professionals.

Progress—Initial work has commenced on the development of a formalized selection procedure and on the categorization of augmentative communication devices. Experience with the Texas Instruments Personal Consultant Expert System demonstration package has led to the development of an experimental expert system based on just five communication devices. This software package runs on an IBM PC/XT/AT or compatible.

In addition, a University of Adelaide student assignment using the Prolog computer language is dealing with the problem of the selection of an appropriate interface for the client.

Assessment of the Effectiveness of a Small, High Quality Speech Synthesizer in Augmenting the Communication of Non-Speaking Individuals

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—The aims of this project are: 1) to assess the effectiveness of the provision of a device with a limited number of phrases on the communication interaction of non-speaking individuals whose physical or cognitive accessing skills do not allow them to operate other speech synthesis devices; and, 2) to demonstrate that the use of a simple low-priced speech synthesizer is of value in increasing communication interaction.

Progress—All speech synthesizers available to us were included for a comparative evaluation if they were portable and able to be accessed by 1 to 8 switches. Those excluded because they are intended for main power operation included: Votrax Personal Speech System, Type 'N Talk, Echo II, and SAM.

Several were excluded because they are not easily used with 1 to 8 switches in direct selection mode. Direct selection was considered important because of the poor physical and/or cognitive accessing ability of our intended client group, and because of the need to maximize the speed of communication.

Those excluded on this basis were: Light Talker, Touch Talker, SpeechPAC, Zygo Talking Notebook, and both Vocriss models. The Elfin My Voice was not available here at the time of the evaluation. The devices remaining for further evaluation were Wolf, Alltalk, and Voice Synthesizer Unit from Technical Solutions.

It was considered important that the voice generated should be of high quality so that any listener could easily understand the message. A comparison of the intelligibility of the three devices was carried out using a shortened version of a test developed by Yorkston and Beukelman.

The shortening of the test was made necessary by the small number of utterances that will be required of the devices tested when being used by the subjects. Three adults with normal hearing listened to eight phrases from each of the devices tested.

Results—The results show that for the three devices tested on each of three adult listeners, intelligibility was highest for the most expensive device (Alltalk) and lowest for the least expensive device (Voice Synthesizer Unit). Since our research requires a device which is highly intelligible to people who may have little familiarity with speech synthesizers, the Alltalk will be used for the remainder of this research project.

Machine Shorthand-Based Speech Prosthesis

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Sponsor: *None Listed*

Purpose—The aim of this project was to produce a speech prosthesis capable of use at natural speech rates, with unrestricted vocabulary, for manually-dexterous speech-impaired persons.

Progress—A prosthesis has been developed based on a stenotype shorthand machine keyboard connected to a speech synthesizer. Using such a system, skilled stenotypists have been able to conduct a free-flowing dialogue at low natural speech rates. The system can be used with the British Panaltype or American Stenograph Keyboard.

Current work is aimed at improving attainable speech rates and the quality of synthetic speech, particularly in the control of prosodic feature.

Implications—As well as being of potential benefit to manually-dexterous speech impaired persons, the system may assist both able-bodied and sight-impaired persons to learn to stenotype, and be applicable in human factors experiments on synthetic speech.

D. Deaf-Blind

The Talking Glove: A Communication Aid for Nonvocal Deaf and Deaf-Blind Individuals

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Sponsor: *Rehabilitation R&D Center, VA Medical Center, Palo Alto, CA*

Purpose—The purpose of this study is to develop a portable communication aid that would permit nonvocal deaf and deaf-blind people to engage in conversation among themselves and with hearing persons.

Progress—A portable communication system, based on the concept of a "talking glove," is being developed to reduce the communication barrier between hearing people and nonvocal deaf and deaf-blind individuals. The system consists of an instrumented glove to sense fingerspelling hand formations, and a pattern recognition algorithm to translate these formations into speech. The two-way communication system also includes a microcomputer module and various user-selectable peripheral devices. These peripherals are selected to transmit and receive information based on the individual's specific communication requirements.

A nonvocal deaf-blind user can transmit synthesized speech to a hearing person by fingerspelling while wearing the glove equipped with sensors. This instrumented glove supplies hand formation information to a recognition algorithm running on the microcomputer, which then identifies the intended letter. Once a fingerspelled letter is determined, the microcomputer sends the data to a speech synthesizer (currently a DECtalk) and the corresponding word is spoken to the hearing person via a miniature speaker worn as a "speech pendant" under the shirt of the nonvocal individual. In effect, the nonvocal user's information output device is a "talking glove."

A hearing person responds to the deaf user by typing on a pocket calculator-size keyboard. The keyboard can be carried in the shirt pocket of the deaf or deaf-blind individual and handed to the hearing person with whom he or she wants to communicate. The small keyboard has a liquid crystal display (LCD) that states the deaf person's name and requests message input from the hearing individual. Data entered on this keyboard is transmitted to the microcomputer module and displayed for the deaf person. An IntroVoice voice recognition system has also been integrated into the system to allow trained individuals to enter messages directly by speaking.

Text generated by the hearing person is displayed for the deaf individual in a variety of ways. For sighted deaf people, text is displayed visually on a small LCD monitor worn as a wristwatch. A deaf person with reduced vision might require that the text be output on a large-print LED display. For a deaf-blind user, the text is sent to a portable multicell mechanical braille display. The braille module fastens to the belt for use while walking and standing, but detaches for desk-top use.

Results—The prototype communication aid has been tested by several nonvocal deaf and deaf-blind persons, and the results are encouraging. Interaction with these individuals has been valuable to the design thus far and will be maintained throughout the development to ensure that the final product incorporates the needs and desires of its potential users. Future research will focus on recognizing Signed English signs and converting these to synthesized speech. This would further improve communication efficiency of the system.

Publications Resulting from This Research

The Talking Glove: An Expressive and Receptive "Verbal" Communication Aid for the Deaf, Deaf-Blind, and Nonvocal. Kramer J, Leifer L, *Proceedings of the Annual Conference for Computer Technology, Special Education, and Rehabilitation,* California State University, Northridge, CA, 335, 1987.

An Expressive and Receptive Communication Aid for the Deaf, Deaf-Blind, and Nonvocal. Kramer J, Leifer L, *Proceedings of the 9th Annual Conference of the IEEE Engineering in Medicine and Biology Society (EMBS),* Boston, MA, (Supplement):20, 1987.

A Second Generation Mechanical Hand Communication Aid for the Deaf-Blind

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Sponsors: *Rehabilitation R&D Center, VA Medical Center, Palo Alto, CA; The Smith-Kettlewell Eye Research Foundation*

Purpose—People who are both deaf and blind experience extreme social and informational isolation. Those deaf-blind individuals who use a tactile version of fingerspelling and/or sign language to "converse" with others enjoy some relief from this isolation.

"Dexter II," a second-generation computer-based electro-mechanical fingerspelling hand, has been developed to enable a deaf-blind person to receive tactile messages from a mechanical hand in response to keyboard input during person-to-person communication, as well as to gain access to local and remote computers and the information they contain.

Progress—The first version of Dexter looked like a mechanical version of a rather large human hand projecting vertically out of a box. A more compact version has now been designed by three graduate mechanical engineering students at Stanford University. Their design, Dexter II, employs DC servo motors to pull the finger drive cables of a redesigned hand, thereby eliminating the need for the pneumatic power source, which had been used in the original version. A speed of approximately 4 letters per second (almost twice that of the first design) can be achieved with the improved device.

In the original version, the microcomputer and associated software controlled the opening and closing of a bank of valves which directed air pressure to specific pneumatic cylinders. The DC servo motors in Dexter II are controlled by pulse-width modulation chips. In both cases, the resultant motion pulls on the drive cables which are the "tendons" of the fingers.

In operation, a message is typed on a keyboard (an Epson HX-20) by an able-bodied person. Each letter's ASCII value is used by the software as a pointer into an array of stored control values. Two to 6 of these control operations, each separated by a programmed pause, are needed to specify the finger movements corresponding to a single letter.

Although neither mechanical hand can exactly mimic the human hand in fingerspelling all the letters (such as the special wrist and arm motions required in J and Z), the fact that the same motions for a given letter are produced is an important factor in interpreting its actions.

Results—Dexter II was first tested by a proficient deaf-blind communicator who provided many suggestions for improving fingerspelling intelligibility. Subsequently, it was introduced to 12 deaf-blind people. Their ability to initially understand Dexter II varied considerably.

Future Plans/Implications—Additional testing will be conducted on the ability of deaf-blind people to use the mechanical hand for extended periods of time, as well as on determining optimal configurations for the letters, and optimum rate of letter presentation.

In the next software design iteration, a finger position editing program will be written. This program will permit the interactive formation of letter-pair transitions. The control information resulting from this phase will be incorporated into the next evaluation of Dexter II. The future implementation of a full 26 by 26 matrix of possible letter-pair transitions would eliminate the need for the neutral position and produce more natural fingerspelling. A faster and more intelligible fingerspelling device is anticipated.

Dexter II is intended to serve a complete receptive communication system, not just a means of receiving information in face-to-face situations. Its ability to respond to computer input means it can be interfaced to a TDD to provide deaf-blind people with telephone communication. It can also be connected to computers to provide improved vocational and avocational potential to the deaf-blind community.

Publications Resulting from This Research

A Robotic Hand as a Communication Aid for the Deaf-Blind. Gilden D, in *Proceedings of the Twentieth Hawaii International Conference on System Sciences,* 1987.

A Robotic Hand Communication Aid for the Deaf-Blind. Gilden D, Jaffe DL, *SOMA*, October, 1987.

Learning Styles and Effective Teaching Technologies for Enhancing the Employment of Deaf-Blind Youth

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Sponsor: *Office of Special Education Programs, Department of Education*

Purpose—This field-based project is attempting to identify and evaluate instructional technologies that take into account the learning style or approach of individual deaf-blind youth, and that facilitate the acquisition of independent living, community living, and vocational skills by multiply-impaired deaf-blind youth.

Progress—Initial phases of the project consisted of: 1) the identification, compilation, and review of existing literature on both "learning styles" and "teaching technologies" relevant to deaf-blind education; and, 2) surveying of special educators and instructional personnel of deaf-blind students about their methods and resources for assessing students' learning styles and for determining effective teaching techniques in a variety of task areas such as perception, memory, concept formation, and problem solving.

The current phase of this 3-year project involves a multi-site qualitative investigation of programs that have gained national recognition for their high success rates of vocational placement and instructional programs. Aspects of each program explored include: 1) the interaction between teacher and student; 2) the programmatic organization of the program; 3) the overall characteristics of the students in the program; 4) the instructional and personality style of the teachers; 5) the participation of families; 6) the retention and reinforcement strategies involved in the program; and, 7) administrative and community support. The investigation included both higher functioning deaf-blind students (such as those with Usher's Syndrome) and more severely involved multiply-handicapped students (such as the Rubella student).

Instructional observations focused on a variety of skill areas, including the four cognitive domain areas mentioned above. The four exemplary programs studied were the Helen Keller School at the Alabama Institute for Deaf and Blind in Talladega, AL; the Helen Keller National Center for the Deaf-Blind Youth and Adults in Sands Point, NY; Project Advance of the Perkins School for the Blind in Boston, MA; and the Texas Educational Service Center, Region XX Program in San Antonio, TX.

The project team spent two weeks at each facility observing, interviewing, and documenting the instructional and learning aspects of the program.

Future Plans/Implications—The data will be compiled and compared to determine whether there are common characteristics or aspects of these exemplary programs which may be of value to other programs concerned with developing effective instructional programs for deaf-blind youth in transition.

XVI. Miscellaneous

Dissemination of Rehabilitation Technologies

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Sponsor: *VA Rehabilitation Research and Development Service (Project #F259-OA)*

Purpose—Our primary goal is to produce guidelines for effective technology transfer of products, processes and findings, designed for investigators involved in rehabilitation research and development. Our secondary goal is to inform policymakers in the VA about aspects of the transfer process than can be facilitated through policy changes.

Progress—During the first year of this 3-year project we gathered information from selected members of the rehabilitation community, technology development centers, and manufacturers. We created a framework for describing the process of transferring rehabilitation technology from the design stage to manufacturing. Next, we surveyed all the projects at the Palo Alto Rehabilitation Research and Development (RR&D) Center and conducted interviews with selected engineers whose projects were in different stages of development.

With this background, we have drafted a *Guide* which is tailored to the roles of Investigators, the Transfer Officer, and the Center Director. It informs readers about the process of technology transfer at the national, center, and project levels; provides general guidelines for designing and conducting projects to enhance transferability of the technology being developed; and suggests specific steps involved in key decision points, such as entering into agreements with manufacturers, making disclosure statements, applying for patents, and arranging licensing.

Preliminary Results—Reviews of the *Guide* have been carried out by investigators in the RR&D Center and by rehabilitation researchers and engineers outside the Center. They indicate that it is thorough and addresses relevant concerns of rehabilitation engineers within the VA system.

Future Plans—Final refinements and revisions were begun in the Fall of 1988, based on feedback from pilot trials and reviews. The *Guide* will be made available to all RR&D engineers at the Center and selectively to others who are involved in rehabilitation development. A report will be prepared and submitted to VA policymakers reporting findings of the study, with recommendations for further improvement in the technology transfer process.

Rehabilitation Effects of Expectation, Reward, and Activity on Subtypes of Schizophrenia

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Sponsor: *Va Rehabilitation Research and Development Service (Project #F515-RA)*

Purpose—The purpose of the proposed research is to investigate the benefits of productive activity in the rehabilitation of patients with a diagnosis of schizophrenia. The key questions are: 1) Does greater expectation for productive activity lead to more productivity? 2) Does greater productivity lead to better rehabilitation outcomes? 3) Does pay act as a reward for schizophrenic patients in a work program leading to greater productivity, greater job satisfaction, and increased self-esteem? 4) Does greater expectation increase the likelihood of relapse and rehospitalization? and, 5) Are subtypes of schizophrenia based on psychological and neurobehavioral measures useful predictors of rehabilitation outcome?

Methodology—In an experimental control group design, 150 patients recruited from the general psychiatric service, including the mental hygiene clinic, with a diagnosis of schizophrenia confirmed by SADS-RDC, will be assigned through stratified randomization (by premorbid history and negative symptoms) to three levels of expectation for work. N: *No Expectation* = 30, *Low Expectation* (10 hours per week required) = 60, *High Expectation* (20 hours per week required) = 60.

Subjects in the *Low Expectation* and *High Expectation* conditions will be offered work through the Incentive Work Therapy Program (IWT); those in the *No Expectation* group will not. The IWT provides up to 20 hours of work per week in a variety of placements throughout the Medical Center, with duties similar to those of regular hospital employees. All subjects will attend weekly group sessions where, across all conditions of expectation, support is provided, conditions of expectations are reinforced, and weekly information on productivity and measures of clinical status are obtained. Research staff will also evaluate productivity through on-site, time-sampled monitoring of attendance and productivity, and through supervisors' weekly evaluations.

For 3 months of the active intervention, subjects will receive weekly pay at a rate of $3.40 per hour of productive activity; and for 3 months, subjects will be asked to work without remuneration. To examine order effects, subjects will be randomly assigned to receive pay either in the first or the second 3 months of their involvement. Subjects in the *No Expectation* control group will also receive payment for verified productive activity during the pay condition of the active intervention. Subjects will be evaluated on demographic, neurobehavioral (negative symptoms, smooth pursuit eye-tracking, Wisconsin Card Sort) and productivity measures at baseline. They will be interviewed at the conclusion of the 6-month intervention and at 12-month follow-up from program entry to assess their clinical status, productivity, and other measures of rehabilitation outcome.

Data analysis employing descriptive and inferential statistical methods will examine main effects, interaction effects, and the predictive value of subtype schemes to answer the key questions of the proposed study.

Implications—Results of this study should provide guidelines for expectation, reward, and amount of activity in planning programs of productive activity appropriate to the rehabilitation of schizophrenic veterans.

Evaluation of One-Way Air Flow Valve Prostheses in Decannulation Procedures for Chronic Tracheotomized Patients

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C417-RA)*

Purpose—This research proposal has two objectives. First, we wish to determine which diagnostic tests can be performed that will be useful in identifying those patients who can be weaned from their chronic tracheotomy. Second, we wish to determine if a new technique using the Passy-Muir one-way valve results in a higher success rate and/or a shorter period of weaning.

Progress—In the eleven months since the project was initiated, 37 patients with chronic tracheostomies have been evaluated. Twenty-eight of these patients were excluded from further study because they did not meet our inclusion criteria. Reasons for exclusion included upper airway obstruction (8), sleep apnea syndrome (2), multiple complicated medical problems (12), and in process of being decannulated (6). Nine patients entered the main part of the study. Four patients were randomly allocated to the standard capping procedure while five were randomly allocated to receive the Passy-Muir one-way valve first. Weaning was successful in all but two of the patients who were randomized. One of the patients who failed was tried with both procedures. The other failure occurred in a patient who died of cardiovascular disease shortly after being randomized. One patient is still on the weaning protocol. The mean time for weaning was 18.8 days (range 14–24) with the one-way valve and 18.0 days (range 8–28) for the standard capping.

Results—We found that weaning is a difficult time-consuming procedure in these patients. In addition, we found that almost all the patients had difficulty following directions such that sophisticated measures of pulmonary function were impossible. Standard measures of pulmonary function do not appear to be helpful in predicting which patients are likely to be successfully weaned. There were wide ranges in the MIP (-14 to -54 cm H_2O), MEP ($+18$ to $+100$ cm H_2O), PEF (21 to 110 L/min) and (FEV_1 0.28 to 1.04 L). The two patients who failed weaning had intermediate values. The most useful measure in evaluating how the patients were doing was the pressure at the tracheal stoma when the patients were breathing through their upper airways. If this pressure exceeded 20 cm H_2O on expiration, or -20 cm H_2O on inspiration, the patient had severe upper airway problems and should not have been considered as a candidate for weaning.

Implications—From this study, we conclude that weaning adult medical patients with chronic tracheostomies is a time-consuming, personnel-intensive process. Our initial impression is that the Passy-Muir technique is better tolerated than the standard plugging technique. Monitoring pressures at the tracheal stoma as the patient breathes through his upper airways is valuable in providing an index of the resistance of the upper airways.

Perceptual and Acoustical Characteristics of Tracheoesophageal Voice: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #C941-PA)*

Purpose—The purpose of this study will be to compare acoustic and perceptual characteristics of tracheoesophageal (TE) voice produced in four different prosthetic/occlusion conditions: 1) using the Blom-Singer Duckbill Prosthesis and digital occlusion of the tracheostoma; 2) using the Blom-Singer Duckbill Prosthesis and valve occlusion of the tracheostoma; 3) using the Blom-Singer Low-Pressure Prosthesis and digital occlusion of the tracheostoma; and, 4) using the Blom-Singer Low-Pressure Prosthesis and valve occlusion of the tracheostoma. Characteristics of speech produced in each condition will also be compared to those of normal speech.

Progress—To date, data has been collected on 13 TE speakers.

Future Plans/Implications—It is anticipated that 20 TE speakers will participate in this investigation. Results of the investigation will enable the speech/language pathologist to determine the prosthetic/occlusion condition best-suited for a given laryngectomee with TE puncture.

Characteristics of Tracheoesophageal Voice in Four Prosthetic/Occlusion Conditions

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C499-RA)*

Purpose—The purpose of the present study is to examine perceptual and acoustical characteristics of tracheoesophageal (TE) speech. Different types of voice prostheses, as well as different methods of occluding the tracheostoma to divert air into the esophagus, will be used to determine if these factors influence perceptual and acoustical characteristics of TE speech. We hypothesize that speech characteristics will be influenced by systematic variance of these factors.

Fifty laryngectomee patients using TE speech will participate in the study. The number of patients in each of the following categories will be controlled: 1) primary versus secondary TE puncture; 2) radical neck dissection versus no radical neck dissection; 3) radiation versus no radiation; and, 4) myotomy versus no myotomy. They will be video- and audio-taped while performing the following tasks: 1) counting to 20; b) sustaining the sound /a/ for as long as possible on three trials; 3) reading words, sentences, and the Rainbow Passage aloud; 4) describing pictures; and, 5) conversing with the examiner.

These tasks will be performed four different times by each laryngectomee: 1) with the Blom-Singer duckbill prosthesis and digital occlusion of the tracheostoma; 2) with the Blom-Singer duckbill prosthesis and valve occlusion of the tracheostoma; 3) with the Blom-Singer low-pressure voice prosthesis and digital occlusion of the tracheostoma; and, 4) with the Blom-Singer low-pressure voice prosthesis and valve occlusion of the tracheostoma.

These four trials will be counterbalanced across all subjects. In addition, a group of 50 normal laryngeal speakers will be video- and audio-taped while performing the speaking tasks.

Three different groups of judges, varying in their level of knowledge about alaryngeal voice, will rate the taped speech samples on a scale of 1 to 7 for the parameters of pitch, quality, loudness, extraneous speaking noise, visual presentation during speech, intelligibility, rate of speaking, and overall communicative effectiveness.

Utilizing the data gathered through this paradigm, we will accomplish the following goals: 1) determine if speech produced using various combinations of voice prostheses and methods of tracheostomal occlusion can be discriminated on the basis of specified perceptual and acoustical characteristics; 2) determine which combinations of voice prostheses and method of tracheostoma occlusion yields speech most similar to that of laryngeal speakers with normal voices on both perceptual and acoustical measures; 3) determine if perceptual judgments vary with judges' expertise level; and, 4) determine if differences exist in judges' ratings and acoustical measures according to the following variables: primary versus secondary TE puncture, radical neck dissection versus no radical neck dissection, radiation versus no radiation, and myotomy versus no myotomy.

Our results will have important clinical implications. They will indicate specific voice characteristics which may need attention in speech treatment following TE puncture. In addition, this investigation will provide information regarding which combination(s) of voice prostheses and method of stomal occlusion yields the most "normal" audible speech. It is hoped that this will assist TE puncture patients and speech pathologists in making a more informed decision regarding speech.

Computerized Treatment of Acquired Reading Disorders

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C324-RA)*

Purpose—The objective of this research project was to develop efficacious, computerized treatment tasks that were suitable to improve deficient reading strategies associated with the lexical route or the phonological route of reading in alexic patients.

Progress—Ten treatment tasks were developed; 5 lexical and 5 phonological. Of each set, 3 were considered basic tasks and 2 were advanced. A total of 15 patients participated in the treatment study, but 4 did not complete the study due to illness. Seven of the 11 patients with alexia with agraphia displayed relatively deficient phonological reading while the remaining 4 displayed involvement of the lexical route as well. Of the 7 patients displaying a larger deficit in phonological processing, all responded significantly better to phonological treatment than to lexical. This treatment response reflected improvements in the deficient route. Of the 4 remaining patients, 2 responded better to the lexical treatment and 2 did not respond to either treatment method.

Results—As an extension of this study, we looked at the use of this treatment with cases of alexia without agraphia; a prelinguistic deficit of reading thought to reflect a deficit at the level of perceptual analysis feeding into the linguistic reading routes differentially. Subtypes of alexia without agraphia include spelling dyslexia (a deficit of visual analysis of whole work units, such that the patient can only analyze stimuli letter by letter), and nonspelling dyslexia. Three patients with alexia without agraphia (one with spelling dyslexia) participated in this reading program. It was observed that the subjects with alexia without agraphia responded differently to the treatment, depending upon the form of reading deficit displayed. That is, subjects of the nonspelling dyslexia type responded favorably to the more analytical (phonological) treatment method; whereas the subject exhibiting spelling dyslexia responded favorably to the more gestalt (lexical) treatment method.

Publications Resulting from This Research

Isolated Lexical Agraphia in a Right-Handed Patient with a Posterior Lesion of the Right Cerebral Hemisphere. Rothi LJG, Roeltgen DP, Kooistra C, *Brain and Language* 30:181-190, 1987.

Hemispheric Specialization for Writing in Right-Handers. Mack L, Heilman KM, Rothi LJG, *J Clin Exp Neuropsychol* 9:31, 1987.

Computerized Treatment of Alexia without Agraphia. Moss SE, Rothi JLG, *J Clin Exp Neuropsychol* 9:39, 1987.

Phonological Alexia with Optic and Tactile Anomia: A Neuropsychological and Anatomical Study. Rapcsak SZ, Rothi LJG, Heilman KM, *Brain and Language* 31:108-121, 1987.

Computerized Treatment of Pure Alexia: An Advanced Treatment Program. Moss SE, Rothi LJG, *J Clin Exp Neuropsychol* 10:30, 1988.

Single-Word Comprehension in Hyperlexic Children. Woeller KKS, Rothi LJG, Armus J, *J Clin Exp Neuropsychol* 10:91, 1988.

Augmentative Communication for Intensive Care Unit Patients: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E927-PA)*

Purpose—Commercially-available augmentative communication devices tend to be cumbersome in size, require considerable movement and effort, have a limited vocabulary, poor storage of information, are difficult to learn in a short period of time, and the communicated messages are difficult for the patient to see. The *Intensive Care Communicator*, developed by Kevin Neelands, was designed solely for patients in intensive care units (ICU), and addresses all of the problems found in other programs.

The major objectives of this project are to determine whether the Intensive Care Communicator program can effectively be employed as a means of communication between patients, staff, and family. Specific questions include: 1) Can an acutely ill patient learn to use a computer program for communication? 2) Can a patient's family and intensive care unit personnel interact with a patient using an augmentative computer program for communication? and, 3) Are there significant differences on the communication satisfaction questionnaire between subjects using the computer program, and are they related to questionnaires supplied by staff and family?

Progress—Results to date indicate that this program is usable as an Augmentative Communication System for patients in Intensive Care Units. Patients, family, and staff all found the system to be reliable and extremely beneficial. At no time was it felt that it interfered with ongoing treatment, nor considered to be in the way. Seven patients have used the program successfully. They ranged in age from 43 to 70 years old, with a mean age of 60 years. Patients remained on the program from 1-15 days, with a mean usage of 5.86 days. Time needed to train individuals to use the program ranged from 15 minutes to one and one-half hours, with a mean training time of 45 minutes. Training of the Intensive Care Unit staff was accomplished in four 20-minute inservices. Three of the 7 patients used the computer program extremely effectively. Subjectively, it appears that age (younger subjects) and severity of illness determine the relative successful usage of the program.

The following concerns of the computer program were noted and corrected during the past year: 1) Emphasis has been placed only on the Five-Switch Program, since it proved to be basic enough for patients to use immediately. Therefore, the single-switch option has not been used, modified, or incorporated into the protocol; 2) Functions have been increased to include an alarm mode, the ability to erase stored messages without re-booting the program, and the ability to change the speed of the cursor from the hand-held unit; 3) The number and letter lines have been eliminated to unclutter the screen and various *Help* screens have been implemented; and, 4) Size of monitor print has been difficult to see for patients with visual disturbances. (An IBM version of this program is now in the process of development which offers larger print.)

Future Plans—An ongoing grant proposal has been submitted to continue testing and adaptation of the augmentative communication computer program for the Apple and IBM computers. Specific questions include: 1) Can a tool be developed that measures the cognitive, motor, and sensory skills necessary for ICU patients to use the augmentative communication computer program? 2) Can word lists and phrase lists be adapted to simplify selection of wants and needs? 3) Can preoperative teaching to postoperative ICU intubated patient-candidates decrease training time, decrease patient stress, and increase quality of life during the noncommunicative period? and, 4) Can improved switch devices increase ICU intubated patients' communication with the augmentative communication computer program?

Design of a New Toilet—Transfer and Access: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Project #E951-PA)*

Purpose—This pilot study is aimed at collecting data on the ease of approach, access, and transfer to and from a wheelchair to a toilet fixture by disabled people capable of independent transfer: paraplegics, low quadriplegics, amputees, etc. Collection of data is necessary for the preparation of a proposal for the design of an accessible toilet.

Methodology—*Task 1: Gathering data from users about preferences in bathroom fixtures.* Gathering of data will be accomplished by reviewing and analyzing a survey published by *Paraplegia News*. This survey is divided into three categories. The first deals with the usage of the toilet, the second the lavatory, and finally, the bathtub or shower. For each category, *Paraplegia News* readers will be asked to comment on their technique of approach, transfer, and usage of the fixture, as well as on the type of assistive devices they have installed if their fixture is not satisfactory. Finally, in addition to personal data, the survey seeks answers to the type of remodeling or modifications readers have made in their homes.

Task 2: Design of full-size toilet fixture prototypes to study access and transfer techniques of disabled people capable of independent transfer. These will be designed based upon the data gathered in the survey and, more specifically, on the manner by which non-ambulatory people transfer to their present fixture, and the problems they experience. The prototypes will then be evaluated with disabled people capable of independent transfer, to study hand and body positions, reaching ability, transfer techniques, and the use of various types of grab bars. This evaluation will follow a protocol using a questionnaire and videotaping of participants. The evaluation is expected to provide the necessary feedback to either validate the prototype or lead to modifications.

Future Plans—Data gathered in this pilot study will be used in the preparation of a developmental proposal.

Computer Applications in Clothing for People with Special Needs

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Sponsor: *VA Rehabilitation Research and Development Center Core Funds*

Purpose—This project seeks to provide a general solution to the individual fitting, dressing, and functional clothing requirements of people with special needs through the application of computer-aided design technology. Our focus is on the generation of accurate digital and graphic representations of flat patterns for use in garment design and construction. We are also investigating different ways of taking human body measurements to address the needs of different populations and to determine the quantity, as well as the quality, of measurements that are necessary to produce a custom fit. We believe that clothing that compensates for functional limitations, and encourages people to dress themselves, can lessen the burden of caregiving, reduce the need for institutional care, and contribute significantly to the quality of life of individuals.

Progress—Since the project's inception, the development team has worked toward applying flat pattern-drafting techniques in a computer-aided design environment. AutoCad (AutoDesk) and Synthesis (TransformerCAD) have been selected as our software tools. AutoCad is a PC-based computer-aided design package; Synthesis, which works in conjunction with AutoCad, allows a designer to change master drawings via information stored on a spreadsheet.

To date, we have developed several basic patterns including a woman's bodice, skirt and sleeve, and a man's pant and shirt pattern. We are now testing the results with anthropometric information collected from able-bodied subjects. Once the basic patterns are proven, we will begin testing with information from subjects with a greater variety of physical needs and characteristics. Finally, we will develop specific garments for use in patient rehabilitation.

We are also developing specifications for making alterations in ready-to-wear garments in addition to recreating an existing pattern for a halo shirt on the computer system so that it can become more readily available to individual patients. The hope is to quantify some of the work that has already been done by health care professionals and independent design consultants while investigating new concepts in custom clothing design.

Future Plans—Future projects include a "visual" questionnaire and clothing-needs survey, and a computer-based tutorial on clothing and dressing for use in post-spinal cord injury patient training. All of these applications will be developed in the Macintosh environment using HyperCard, an authoring tool and information organizer.

Publications Resulting from This Research

CAD-Clad: Computer-Aided Clothing Design for People with Special Needs. Holloway KJ, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:694-696, 1987

Beyond Velcro: A Student Project in Human Factors and Design for People with Special Needs. Holloway KJ, *Proceedings of the 10th Annual RESNA Conference*, San Jose, CA, 7:368-370, 1987

Computer-Aided Design Technology: Applications in Rehabilitation. Holloway KJ, *Proceedings of the 4th National Conference on Clothing for People with Special Needs*, Tuscaloosa, AL, 126-129, 1988.

Transparent Access to Sources of Computer-Based Information

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Sponsors: *VA Rehabilitation R&D Center Core Funds; Digital Equipment Corporation*

Purpose—KIOSK, a general-purpose software program, has been developed to demonstrate how the barriers to obtaining computer-based information can be reduced, benefiting both able-bodied and disabled people.

Progress—The KIOSK software has been designed to run on both 8-bit and IBM-PC compatible computer systems. A DECtalk Speech Synthesizer completes the hardware system and provides a friendly interface between the computer and its data and individuals requesting information.

KIOSK is a flexible Authoring System for the DECtalk Speech Synthesizer and can be used to disseminate a variety of information. The information provider designs this structure and provides the text files to be spoken by the program. In operation, the user uses his/her home or business Touch-Tone telephone to dial the telephone number of the DECtalk Speech Synthesizer. The equipment answers the telephone and KIOSK then mediates the interaction between the caller and the computer. The software: 1) permits the DECtalk to speak computer-based text files; 2) receives data from the DECtalk on which Touch-Tone keys are pressed by the caller; and, 3) works with a knowledge of a structure for presenting the text files.

Currently, the interaction between the caller and the computer is accomplished through a series of computer-initiated speech output and caller responses. The user is presented with either instructions, information, or choices. The caller's response to a choice is made by pressing the Touch-Tone key corresponding to his/her selection. The DECtalk recognizes the keypress and causes the program to branch in an appropriate manner based upon the response. This process is continued with the computer sending information from text files to the DECtalk that is spoken over the telephone, and with the user making choices on how the interaction is to proceed.

Results—One current application being demonstrated at this facility is a voice-output version of this Center's Progress Reports, which are descriptions of the operation of this Center and its projects.

An unexplored application of KIOSK is the voice output dissemination of information that would normally be presented in traditional printed newsletter format or general consumer type information.

Future Plans/Implications—KIOSK makes it possible for individuals without access to or knowledge of computers to obtain computer-based information. The substantial barriers of having to buy and learn how use a computer for obtaining computer-based information are eliminated. Visually-impaired people could benefit from this type of access—and it serves able-bodied individuals equally well. In addition, modem communication could be added to supply the same information to people who have computer systems, including hearing-impaired individuals.

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Extension of this work will allow a computer system to mediate the exchange of information between the caller and the information contained in a remote database such as CompuServe or computer-based bulletin board systems.

Publications Resulting from This Research

Transparent Access to Sources of Computer-based Rehabilitation Information. Jaffe DL, in *Proceedings of ICAART '88*, Montreal, 394-395, 1988.

A Voice-Output Questionnaire Administrator

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Sponsor: *VA Rehabilitation R&D Center Core Funds*

Purpose—This project employs a computer-controlled DECtalk speech synthesizer to administer, score, display the results of, and maintain data from, a standard psychological test (POMS, the Profile of Mood States) for visually-impaired and blind individuals.

Methodology—To measure and compare the mental state of individuals, the Bipolar form of the Profile of Mood States (POMS) has been developed by the Educational and Industrial Testing Service to quantify 6 selected bipolar subjective mood states. In this test, each mood consists of 2 extremes, one represented by the positive aspects of the mood, the other by the negative aspects (such as happy-sad). Each of the 6 moods (composed-anxious, agreeable-hostile, elated-depressed, confident-unsure, energetic-tired, and clearheaded-confused) are measured by analyzing the test-taker's level of agreement to positive and negative mood-indicator phrases such as "cheerful" or "downhearted." While POMS was developed to evaluate established mood states and feelings reported by both normal and psychiatric patients, the principal contemplated use of this test at the Western Blind Rehabilitation Center (WBRC) is to evaluate the relative effectiveness of various training programs in reducing negative moods, while enhancing the positive ones.

The POMS test cannot be administered in the traditional manner to patients who are blind or have visual impairments, since neither group has the visual acuity to read the individual phrases, nor the ability to indicate their choice on the answer sheet. Currently, a staff member reads the phrases to these individuals, queries them for their response, and then fills in the appropriate box on the answer sheet. Later, the answers are hand-scored and a profile produced. Although the time for a sighted person to take the test is only 5 minutes, the staff time required to administer the test to a WBRC in-patient is often double or triple this. Also, the current manual method of scoring and graphing the results is time-consuming.

Progress—The prototype system consists of an IBM XT compatible computer with printer, a DECtalk Speech Synthesizer, and appropriate software. The DECtalk unit has been chosen because it produces speech which is readily understood by those who have no computer experience.

During test-taking using the DECtalk, the software first provides verbal instructions to the patient and then starts the test. Each mood phrase is presented in turn, and a response is solicited. Responses are made by the patient by either pressing a key on a standard keyboard or set of large mushroom-shaped buttons. If, after a given time, no answer is received, the computer reissues the phrase. All patient responses are confirmed, and can be changed if a mistake is made.

At the completion of the test, the computer performs all the necessary scoring, collation, and computation required to produce a dated graph of the mood state profile. This result is then compared to others taken previously, and is eventually placed in the patient's medical record.

Verbal administration of this test takes about 15 minutes; computerized administration requires 5 minutes. Scoring and printing of the results takes an additional minute or two; an appreciable saving over the 5-minute manual method. Results are more accurate, since human bias is eliminated.

Results—The initial software phase of this project has been completed. The first volunteers and test subjects have been selected and testing has begun. No conclusions can be made as to the accuracy or repeatability of this method of testing.

Future Plans/Implications—Two positive results are anticipated upon completion of the pilot phase of this project. First, the project will provide the Western Blind Rehabilitation Center with needed data concerning the effect of the courses and therapy it provides to its patients. Second, it will provide information on the utility of computer-based speech synthesizers in administering psychological tests to visually-impaired and blind individuals. This data should also prove useful in the development of other systems that disseminate information to callers in a similar manner.

Research into Design Requirements for Access by Children with Physical Disabilities

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Sponsor: *The Channel 7 Children's Research Foundation of SA, Inc.*

Purpose—This research was undertaken because of difficulties experienced in designing school buildings to be accessible by children with physical disabilities. No previous research had produced design data for access to the built environment by young people with disabilities. The hypothesis of this study was that the physical access needs for disabled children were not the same as those for disabled adults or able-bodied children, and the extent of their requirements could be defined.

Progress—Two hundred and eighty-eight children, aged 3 to 18 years, including 179 having physical disabilities, were each tested at 30 test stations. Seventy-two variables were measured for each child, relating to mobility, reach and force capacities, and size.

Results—The physical capabilities of disabled children, aged 3 to 18 years, are significantly less than the capabilities of disabled adults and able-bodied children of the same age. Design data are available as results achieved by the most able 80 percent of subjects in each age and disability group. Twenty-one design guidelines have been obtained to enable designers of the built environment to cater to the needs of young people with physical disabilities.

The significance of this research is that a body of empirical data now exists for determining the design requirements for access to the built environment for young people with physical disabilities.

Future Plans/Implications—It is proposed that a standard be developed which will lead to improved access to the built environment for young people with physical disabilities. The report recommends further research before a Building Access Standard for disabled children would be complete (suitable step geometry, speed and distance capabilities on level and inclined surfaces, suitability of adult handrails, wheelchair flexibility, and signage).

Publications Resulting from This Research

Ergonomic Design for Physically Disabled Children, Parts 1 and 2. Bails JH, Seeger BR, Kilkenny: Regency Park Centre, 1988

Development of a Data Management System for the Family Asthma Rehabilitation Program (FARP)

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Sponsor: *Private Donation to the Family Asthma Rehabilitation Program*

Purpose—The objectives of the project are twofold: 1) to establish a data management system suitable for the management and evaluation of FARP activities; and, 2) to examine the medical, psychological, and demographic factors that influence the effectiveness of an in-patient asthma treatment program.

Progress—The project involved two phases. Phase One consisted of designing a database system for the program. Design activities included the review of current data collection methods and the development of computer-compatible inventories. The inventories encompass demographic information, medical indices, and the psychosocial adjustment levels of the child and family. Program computer resources were reviewed and upgraded for the establishment of a data entry and data maintenance system.

Phase Two of the project involved the implementation of the database system. The implementation activities include: 1) teaching staff to administer measures and manage data on the computer; 2) monitoring system activities to ensure fidelity of system design; and, 3) initiating descriptive and evaluative research.

Parallel to the implementation procedures, the project developed appropriate fitness measures for the program. Presently, both phases of the project are completed. Present activities involve preparing papers for publication that will present findings from the project to date.

Ergonomic Guidelines for Arrangement of Work Situations for Handicapped Persons

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—The purpose of this project is the definition of ergonomic guidelines for structuring designs related to a generally-used ergonomic designing technique.

Progress—After a preliminary study and a "case study," there is now a redefinition of the research questions taking place. Specific problem areas on which the research will focus, are: 1) the research instrumentarium for the situation analysis (i.e., What is especially missing: are job data being considered which relate to the physical and psychological possibilities and restrictions of disabled people?); 2) improvement of the evaluation method for the evaluation of function disruption and the ability to obtain a more differentiated picture; and, 3) specification of the task allocation method in order to make a better argumented choice from already existing aids.

This study has been conducted in cooperation with the University of Twente, Dept. for Design WB; State University of Groningen, Dept. of Rehabilitation; Rehabilitation Centre Het Roessingh.

Publications Resulting from This Research

Ergonomische richtlijnen m.b.t. de inrichting van werksituaties voor mensen met een handicap. Van der Star A, *et al.*, Case Study Report, University of Twente, 1987.

An Interdisciplinary Approach to Build Devices to Aid Handicapped Children

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Sponsors: *Louisiana State University School of Medicine; National Science Foundation (Grant EET-8807522)*

Purpose—The need to provide 88 handicapped children enrolled in the Caddo School for Exceptional Children (CSEC) with reasonably-priced technical aids to make them more independent, prompted us to develop a cooperative project involving LSU Medical Center at Shreveport, the CSEC, and Louisiana Tech University in Ruston, Louisiana. The objective of this interdisciplinary program is to provide opportunities for undergraduate engineering students to design and fabricate electrical and mechanical devices to assist the handicapped students at CSEC. Each project will be a "custom-design," suited to the need of an individual handicapped student or group of students with similar physical or cognitive limitations. Each device will be designed and built by 1 or 2 engineering students who will also implement the trial use of the device and make modifications as required for its successful use. Thus, completion of these projects will be a valuable "real world" experience for the students, and will provide a unique service to the community.

Progress—A videotape documenting the limitations and potentials of handicapped students has been prepared. This has allowed the engineering students located at Louisiana Tech to become familiar with the design problems. Several devices have already been built and others are being constructed. Examples of these are:

1) *Knee Flexion Alarm.* This device was designed for a student whose knee, when flexed beyond a certain angle, becomes unstable, causing the student to fall. An electronic device was built that can be attached to the long-leg braces to provide an audio signal when knees are in excessive flexion when walking.

2) *Microswitch for Toys.* It has been shown by many investigators that through purposeful play, a child develops physically, emotionally, cognitively, and socially. Such developmentally-appropriate play can often be provided by low-cost, battery-operated toys and commercially-available games. However, most of these toys require some simple modifications, often in the switching unit, before they can be used by children with limited motor control. We have developed several microswitches that can be activated by a very small force or with limited limb motion.

3) *Robotic Aids.* Robotic aids can give children with severe motor impairment increased control over their environment and increased independence, thus significantly improving the quality of their lives. Plans are underway to use robots as adaptive tools to decrease the severely disabled student's dependence on others for various functions such as feeding, movement, and control of environment (e.g., opening doors) and appliances.

4) *Environmental Control Unit.* An environmental control unit (ECU) allows a handicapped individual to control many appliances (e.g., lights, radio, TV, telephone, washer/drier), and make them more accessible. Some devices now under construction will be based on infrared or sonar systems. Individual units will vary in operation, number and type of appliances controlled, and portability.

5) *Computer Game I/O Interface for Apple II and IIe.* The purpose of this device is to allow access to the input/output connector of the Apple computer's game board so that capabilities of existing programs are available to the handicapped children. This interface box has already been built and is presently being field-tested.

Future Plans/Implications—This project will provide disabled children with an improved educational experience and a more independent and satisfying living condition, while undergraduate and graduate engineering students will gain valuable experience in the design, manufacturing, and implementation of prototype devices for mentally and/or physically disabled children. This "real world" experience will generate motivation and foster an engineering education with a unique sense of purpose and pride as well as providing the institutions involved with an opportunity to perform a unique service to the community.

Many of these projects were part of several design courses in the Department of Electrical Engineering at Louisiana Tech; thus they provided an infrastructure for the curriculum in the school of engineering.

Progress Report for the PEER (Programs that are Exemplary in Education and Rehabilitation) Regional Network

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The PEER Regional Network is designed to promote the use of proven, effective programs and practices among educators and rehabilitation professionals. The project is a resource for any individual or organization providing services in Rehabilitation Services Administration Region II (New York, New Jersey, Puerto Rico and the Virgin Islands). Using a specific, uniform evaluation, the PEER Regional Network validates selected programs, formally recognizes those that are exemplary, and provides technical assistance to organizations seeking to replicate exemplary program models.

The current focus of the PEER Regional Network is on programs that provide either transition or supported employment services to youth with disabilities. Special efforts are being made to validate and formally recognize programs that are serving individuals with learning disabilities and emotional disorders. Emphasis is also on programs that are in least restrictive environments.

Progress—During the first two years of the project, activities focused on developing a system which would identify exemplary programs and practices on the basis of documented outcomes. As part of this process, an advisory board of state directors, advocates, researchers and trainers was recruited to give direction to the project and eventually participate in the selection of exemplary programs.

After an extensive review of the literature and input from the advisory board, several detailed program validation questionnaires were developed. The project has reviewed over 50 programs, using these evaluation instruments. Of these 50 programs, the PEER Advisory Board has recommended 8 programs as "potentially" exemplary. After site visits, all 8 programs were determined to meet the criteria of exemplary status.

Results—A major component of this project is the dissemination of information. Dissemination involves informing those in the field of the purpose of the PEER Regional Network, as well as highlighting programs identified as exemplary. The project is actively informing Region II about the programs that have been selected by PEER.

Future Plans/Implications—Following the identification of exemplary programs, the project provides technical assistance. The project encourages exemplary programs to provide assistance, with the support of the PEER Regional Network, to other programs interested in adopting innovative service delivery components. This technical assistance is meant to help improve service delivery at adopter programs.

One of the most significant features of the PEER Regional Network is its flexibility to respond to the needs of the field. The project is set to work in any priority area specified by the funding agency. Although the project is currently working with transition and supported employment programs, this emphasis could be expanded in future years. However, the project will continue to validate programs in all previously identified priority areas.

Evaluation of Rehabilitation Technology

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of the Rehabilitation Engineering Center (REC) is to develop systematic methods and supporting information that will help disabled persons, clinical prescribers, and third-party payers to accurately and effectively select and apply rehabilitation technology.

Methodology—The Center will be conducting research into existing rehabilitation systems to identify factors that influence both selection and long-term use of products. Practices under study include product design criteria, testing methods, clinical assessment techniques, third-party purchasing guidelines, and user selection habits. Based on information derived (and published) from those studies, the Center staff will develop uniform methods to train clinicians, users, and payers to make appropriate choices.

A major supporting role is being played by ECRI, an internationally recognized company providing product performance information to the health care industry. ECRI will be compiling and listing comparable features of selected rehabilitation products, conducting and publishing assessments of product safety and performance, and publishing a variety of newsletters and bulletins that will furnish comprehensive selection information to providers of rehabilitation services. The National Rehabilitation Hospital (NRH) staff will conduct and manage clinical evaluations and assessments of product usefulness, utilizing patients and clinicians at NRH and cooperating clinical centers. The REC is also monitoring the development of test methods and consensus performance standards at a national and international level and will review them in periodic newsletters.

Progress—Models for product demonstration and in-service training and multimedia modules are being developed and will be presented at appropriate conferences. Direct consultation on evaluation methods and user acceptance criteria will be offered to manufacturers to aid in the development of improved products. Human factors design criteria are being developed to enhance applicability of general consumer goods to special needs.

An Exemplary Model of Intensive Technology Intervention into Private Vocational Rehabilitation Settings

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Sponsor: *Social Security Administration*

Purpose—The purpose of the research and demonstration grant is to clarify and optimize the mechanisms for linking rehabilitation technology services with traditional vocational rehabilitation services. The Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) beneficiary, often difficult to place because of well-known disincentives, is being used as the demonstration model client in an intensive exercise of broad-based technological intervention measures. Working very closely with a "key counselor" from the National Rehabilitation Hospital (NRH) Vocational Rehabilitation Service and with the client's primary therapists, the staff of the NRH Rehabilitation Engineering Service provides suggestions for technological assistance; identifies products and their sources; designs, modifies and fabricates custom devices and workstations; and provides intensive client followup.

Progress--To date, the study has shown through placement in "substantial gainful activity," that intensive technology intervention into traditional vocational rehabilitation services is most effective when appropriately timed in relation to other rehabilitation activities. Research continues toward identifying the optimal stages for technological intervention. Early experiences in the program indicate that success at utilizing technology occurs most commonly when inserted at one of two stages: during initial client screening, and after traditional rehabilitation interventions have prepared the client mentally and physically for return to work. Input from rehabilitation engineering during the screening process has resulted in identifying a broader range of options for the client, with information ranging from computer access to small engine repair. Intervention at a later stage has enabled a chosen goal to be realized through modification and optimization of furnishings and equipment at the worksite, as well as fine-tuning of ancillary needs such as home-modification and transportation.

Delphi Survey and National Invitational Conference on the Primary Health Care Needs of Persons with Physical Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The National Rehabilitation Hospital organized the first national invitational conference on the post-rehabilitation primary health care needs of persons with disabilities, which took place September 28-29, 1988, in Washington, DC. A small group of invited experts on disability-related primary care: 1) reviewed current research on the use of, and access to, primary health care services by disabled persons; 2) identified innovative approaches to the delivery and financing of primary health care services for disabled persons; and, 3) proposed an agenda for additional research on disability-related primary care.

The experts invited to the conference included persons who have made substantial research contributions to the field of disability-related primary care; persons who are active in the provision of primary care for disabled persons; and persons who are in policymaking positions that bear significantly upon issues of primary care for the physically disabled population. Several professions and academic disciplines were represented at the conference, including rehabilitation medicine, geriatric medicine, health care administration, health policy, medical sociology, medical economics, law, and health insurance. Representatives of the public and private sectors included representatives of disability organizations and disabled persons.

The conference was organized around the following four areas concerning the health status and health care needs of persons with severe physical disabilities: 1) the high utilization of inpatient hospital care by disabled persons; 2) the health-related problems of aging with a disability; 3) access to primary care services for persons with disabilities; and, 4) innovative approaches to the financing and provision of post-rehabilitation primary care.

The conference planners used a three-stage Delphi survey procedure to identify the highest priority issues in each of the areas to be addressed at the conference. Each of the experts at the conference were asked to participate in the Delphi survey.

Progress—In the first stage of the Delphi, the experts were asked to specify what they considered to be the five most important issues in each of the four areas of the conference. This was done in the format of an open-ended questionnaire. The issues specified by the respondents were then reviewed, analyzed, and collated by the National Rehabilitation Hospital (NRH) research team. An attempt was made to list every issue mentioned by the experts.

In the second stage of the Delphi, the respondents were asked to rank-order what they believed to be the top five issues from the list of issues compiled in the first stage. The results of the second stage were tabulated, and a prioritized rank-ordering of the issues for each of the areas was established. In the third and final stage of the Delphi, respondents were sent the results of the second stage and asked, given the priorities of their colleagues as a group, to complete one final rank-ordering of the issues. This final stage was important in the process of consensus-building among the experts in the field.

Results—Delphi results demonstrated a consensus among the experts on the most important issues in disability-related primary care and were presented at the Conference.

Future Plans/Implications—The results of the Delphi are currently being prepared for publication. They will serve as the point of departure for discussing the focal areas of the conference.

A Capitation-Financed Managed Health Care Program for Working-Age Persons with Severe Disabilities: A Feasibility Study

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Sponsor: *The Robert Wood Johnson Foundation*

Purpose—The purpose of this study was to determine the feasibility of developing a managed health care program for working-age persons with severe physical disabilities in the Washington, DC metropolitan area. The target population for the proposed program included persons of ages 18-65 living in Washington, DC, suburban Maryland, and Northern Virginia who have the following severe physical disabilities: brain injury, cerebral palsy, major amputations, multiple sclerosis, muscular dystrophy, post-polio, spinal cord injury, spina bifida, and stroke. The program, as initially conceived, was to be based on capitation financing (i.e., the provision of a comprehensive set of covered services to the enrollee during the period of enrollment in exchange for a fixed, prepaid amount of money).

The feasibility study had the following three major objectives: 1) to conduct a market survey of members of target population to determine their health care needs, their health care utilization, their health insurance coverage, and their willingness to participate in a managed care program; 2) to assess the willingness of public and private sector payers to participate financially in a capitation-financed managed health care program directed to the needs of the target population; and, 3) to determine the financial feasibility of the program based on the results of the market survey and consultation with potential public and private payers.

Progress—Initial identification of potential members of the target population was made through the assistance of 18 consumer organizations in the greater Washington, DC area. The mailing lists of these organizations yielded the names and addresses of 993 persons who identified themselves as being members of the target population. A 20- page survey instrument, based, in part, on questions from two major national surveys, was mailed to the 993 self-identified disabled persons. A total of 607 (61 percent) usable surveys were received.

Cross-tabulations have been run on the data and the results have been weighted to approximate more closely the prevalence of disabilities in the general population. Concurrent with collection and analyses of data from consumers, a series of meetings was held with third-party payers of health care services to determine their interest in participating in the program and to identify problems anticipated in implementing such a program.

Results—The preliminary results from survey data analyses have yielded profiles on: 1) demographics; 2) health and functional status; 3) health care utilization; 4) health insurance coverage; and, 5) preferences for managed care. Results from the analyses completed indicate that the majority of respondents prefer some form of managed care program offered by providers who are specifically knowledgeable about their disabilities; however, most were clear in stating that they want to maintain control over decisions affecting their health care.

Results from meetings with third-party payer representatives clearly indicate that a capitation-financed program is not feasible at this time. These representatives did, however, indicate their interest in considering a managed care program using a preferred provider model (in which the consumer's current health insurance program would negotiate with the managed care program on a discounted fee basis for the provision of services to disabled persons who enroll in the program). Although a number of problems have yet to be resolved, this approach appears to be acceptable to both consumers and payers.

Future Plans/Implications—Additional analyses of the survey data, including multivariate analyses, will be completed to assess the determinants of costs, quality, and access to care for disabled persons. Funding has been requested from The Robert Wood Johnson Foundation to support a one-year technical design and development stage, and a six-month implementation stage before establishing the managed care program.

Rehabilitation Technology Electronic Database Development

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Sponsors: *National Institute on Disability and Rehabilitation Research; Apple Office of Special Education, Apple Computer, Inc.*

Purpose—Activities in this area are designed to: 1) explore and develop electronic media as an efficient, economical, and timely media for information dissemination; and, 2) use these media to increase the availability of useful information in the rehabilitation technology field.

Progress—Two database development projects were initiated this year. First, the Trace Center developed a version of the AbleData assistive device database to run under HyperCard on the Macintosh. The Hyper AbleData program eliminates the need for the user to become familiar with the 4,000 word thesaurus before going on-line, by presenting it as a hierarchical outline structure with headings that can be expanded and collapsed at will by pointing and clicking with the Macintosh mouse. The user can also search by manufacturer name or product brand name. The HyperCard program provides fast search and recall times for locating items among the over 15,000 entries in AbleData. It is anticipated that a distributed form of Hyper AbleData could greatly increase the utilization of the database.

The second database development project is the creation of a HyperCard version of TraceBase. This database will provide information on communication, control and computer access, including not only products but also publications, services, clinical and research programs, as well as information briefs, discussions of funding, and definitions of terminology. The HyperCard environment allows for the establishment of a network of context-sensitive links among the data, provides fast search times for locating items, and permits the use of a graphics based "point-and-click" user interface. The Trace Center is also exploring the feasibility of using artificial intelligence (AI) techniques to improve access to this large and varied body of data. Both HyperCard programs were initially presented at ICAART in Montreal and were well received. Versions of both programs which are IBM-compatible are currently under development.

As part of the distribution strategy for information in electronic form, the Trace Center has established the Cooperative Rehabilitation Technology Information Network (CO-NET). This network consists of about 100 sites which serve as Prime Dissemination Points. These sites will receive the Trace Center's information bases, such as Hyper AbleData and Hyper TraceBase on Compact Disc-Read Only Memory (CD-ROM), for their own reference, and for distribution to other organizations, professionals and consumers. The Prime Dissemination points were invited to participate based upon their high level of interest and activity in the area of information dissemination and for their ability to distribute widely any information they receive.

Future Plans—The distributed forms of Hyper AbleData and Hyper TraceBase will be made available on CD-ROM through CO-NET and through the Trace Center's Reprint Service.

Quantification and Modeling of Cognitive Development in Young Children as Exhibited in Mouse-Operated Drawing Tasks

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The project was designed to perform detailed observations of the learning patterns of young children engaged in computerized and non-computerized drawing tasks, and to determine if there is evidence that cognitive skills acquired in computerized drawing will carry over to non-computerized drawing. Computerized drawing included the ability to create and manipulate objects using the mouse. Measurement of cognitive level was made by standard psychological tests administered before and in the middle of testing. Blind ratings of salient drawing characteristics were performed by a group of observers.

Progress—Data from 39 subjects (ages 3 to 6) has been collected. The drawings were rated on a 7-point scale depending upon how recognizable and adult-like the representations were. Ratings showed a consistent improvement in drawing by hand after subjects had had experience drawing with the mouse.

Future Plans—Results are now in preparation for publication.

Patterns of Knowledge Utilization

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Knowledge Utilization Laboratory at the Pennsylvania College of Optometry has been awarded a 3-year grant to investigate patterns of knowledge utilization. Collaborating with the College are the Research and Training Institute at the Human Resources Center in New York and the West Virginia Research and Training Center at West Virginia University.

The products expected for each year are as follows: *Year 1.* Knowledge utilization state-of-the-art review; a profile of information uses by consumers who are disabled and their families; and, a profile of rehabilitation and general information services.

Year 2. Results of empirical research on information giving and information access strategies.

Year 3. Satellite telecast on information giving and information access strategies.

Methodology—The researchers will use an interdisciplinary approach to identify the optimum strategies for increasing information access and knowledge utilization among people who are disabled, their families, and information providers.

Wichita Rehabilitation Engineering Center

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Grant year 1987-88 was the culmination of the 5-year cycle of the Wichita Rehabilitation Engineering Center (REC). The Wichita REC is a consortium of The Cerebral Palsy Research Foundation of Kansas (CPR) and the Wichita State University College of Engineering (WSU). It is mandated by its funding agency, the National Institute on Disability and Rehabilitation Research (NIDRR), with the enhancement of the vocational opportunities of persons with severe disabilities. The CPR and WSU have a 16-year history of collaborative research that has resulted in the validation of the theory that severely disabled people can be productive in mainstream and supportive work environments through the utilization of rehabilitation technology.

Results—During the grant year 1987-88, the Wichita REC perused 11 discrete research projects devoted to the following generic areas: 1) development of standard and assessment indicators for worksite modifications for disabled persons; 2) creation of a body of knowledge relative to worksite modification in order to enhance the productive employment of persons with disabilities; and, 3) definition and assessment of those independent living skills required to sustain an individual at his or her home in order that employment can become a more feasible option.

The 11 projects successfully completed during the past 5 years are designed to provide a source of information to allow professional persons providing technology services in the field to make cost-effective decisions relative to the disposition of their clients in independent living and vocational environments. Utilizing the facilities of CPR, including Center Industries Corporation, the HUD Timbers Residential Complex, and The Daniel M. Carney Rehabilitation Engineering Center, combined with the extensive laboratories of The Wichita State University, the Wichita REC is in a unique position to develop theoretical models of rehabilitation technology. It is also in a position to validate these models in order to insure their replication in a service delivery environment.

Implications—The Wichita REC is committed to a multi-disciplinary approach to solve the problems confronting the population it is dedicated to serve. The College of Engineering contributes a PhD-level facility representing the disciplines of industrial, electrical, and mechanical engineering. CPR furnishes staff involved with the traditional disciplines of speech/language pathology, physical therapy, psychology, special education, and social work. Additionally, CPR provides a staff of highly competent engineers who have dual responsibilities in both research and service delivery.

The reader is encouraged to contact the co-directors of the Center for specific information relative to the results of the 11 research projects outlined above. The Center publishes a document entitled *The Engineering Tech-Brief,* which presents, in layman's terms, pragmatic solutions to problems experienced by severely disabled people in a host of environments. In addition, it publishes annual reports in both written and video form.

Brain Stimulation Analgesia in the Control of Chronic Pain

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Sponsor: *National Institutes of Health*

Purpose—The purposes of the study are to: 1) assess the effectiveness of chronic electrical stimulation of midbrain sites for the relief of chronic pain in humans; 2) evaluate the efficacy and mechanisms of traditional narcotic analgesia and compare these to chronic electrical stimulation of midbrain sites; 3) validate experimental models of pain and their potential diagnostic use in chronic pain patients; and, 4) determine and compare the impact of both traditional narcotic and chronic electrical stimulation therapies on the functional, intellectual and emotional well-being of these patients. The effects of chronic brain stimulation in surgical patients will be compared to the effects of narcotics previously administered to patients, and to effects of narcotic regimes in non-surgical chronic pain patients. In addition, the effects of narcotics on perceptual and neural mechanisms of experimentally-induced pain will be assessed in pain-free volunteers.

Results—The results from two patients this year continue to support previous findings from this project. Morphine significantly decreased the magnitude of both low back pain and experimentally-administered heat pain, and this effect was reversed by naloxone. Comparison of these results to those found after deep brain stimulation suggest that deep-brain stimulation analgesia is not opioid-mediated, and is either less potent than morphine analgesia, or follows a different course.

A second study compared the influence of the narcotic fentanyl on reaction time measures to heat pain in normal subjects to results found previously with chronic pain patients. The results show that fentanyl decreases the magnitude of both first and second pain sensations in a manner similar to decreases found in chronic patients after administration of morphine.

Biofeedback Using Home Computers

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The Rehabilitation Centre, Ottawa, Ontario, Canada K1H 8M2

Sponsor: *The Rehabilitation Centre, Ottawa, Ontario, Canada*

Purpose—The purpose of this project is to make use of home computer technology to provide biofeedback. In some circumstances, people do their own training at home, thus permitting the clinician to have a record of each treatment and to have a progress report. It also permits the patients to do their exercises more often and to recuperate faster.

Progress—A junction box has been constructed that accepts inputs from switches or from a load cell and is connected to the joystick input of a computer. A switch can be used to monitor range of movement. The load cell can be used to monitor the amount of pressure required to turn on a switch. A child with cerebral palsy is currently using this system to train her leg muscles.

Future Plans—To replace all the functions of a joystick by training equipment so that it will be transparent to the computer software.

Development of Lightweight Ice Picks for Sledge Hockey

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Sponsors: *Support Amateur Sports Fund, Sport for Disabled—Ontario; Variety Village Sport Training and Fitness Center*

Purpose—Sledge hockey is becoming a very popular winter sport. Although designed primarily for disabled participants, it is also enjoyed by the able-bodied. The ice picks currently available are modified from standard hockey sticks by shortening the shaft and embedding a sharp pick in the end. The use of this equipment poses several problems, particularly for younger athletes. The pick is very long and sharp and could potentially cause serious injury to another player. The picks are also difficult to handle because it is necessary to change one's grip from picking to shooting the puck. The final problem relates to the weight of the picks, which are quite heavy, making it difficult for younger athletes to manipulate the equipment successfully.

Results—The sledge hockey pick has been redesigned to make it safer, lighter, and easier to use. The long pointed pick has been replaced by a series of short jagged edges (similar to the toe of a figure skate), thus substantially reducing the possibility of stabbing injuries to other players.

The shaft of the pick has been fabricated from metal, which makes it smaller and lighter. The addition of a handle allows players to pick and play the puck without altering their grip on the shaft of the pick. Playing is much easier and safer since the possibility of a player dropping the pick is reduced.

The new design of the sledge hockey pick was evaluated during a recent winter sports camp. The new picks were enthusiastically received by all of the participants. The coaches observed a decrease in the level of frustration experienced by new players, as well as increased mobility and endurance among all the athletes.

An Infant Crib for Use by Physically Disabled Parents, Especially Those Using Wheelchairs

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The Rehabilitation Centre, Ottawa, Ontario, Canada, K1H 8M2

Sponsor: *The Royal Ottawa Health Care Group*

Purpose—The purpose of this project was to design and evaluate an infant crib which could be used by a wheelchair-bound parent or by a parent with a physical disability such as arthritis. It was necessary to enable a wheelchair-bound person to come close to the crib to allow safe handling of the infant.

Progress—Two prototype cribs have been constructed. One prototype is being evaluated by the parents of a young infant where the mother is wheelchair-bound. The second prototype is used for research and for the performance of modifications and changes. Some difficulties have been encountered in complying with the Canadian Crib Regulations as published by Consumer and Corporate Affairs, Canada. These regulations stipulate that the locking mechanism shall require two separate, positive, and simultaneous actions on the part of the user to release the mechanism. This contrasts with U.S.A. regulations which offer the alternative of requiring a minimum force of 10 pounds to activate a single release mechanism. Since many wheelchair-bound parents will have reduced strength and dexterity in their arms and hands, more work will be required to come up with versions of our crib which satisfy the appropriate government regulations and which can be used by our clients.

Future Plans—We plan to continue the development of this crib along the lines mentioned in the previous section, until all outstanding problems have been solved.

Publications Resulting from This Research

A Crib for Use by Wheelchair-Bound Parents. O'Riain MD, Layeux G, *Proceedings of the S.M. Dinsdale International Conference in Rehabilitation*, 50-51, 1988.

The Design of a Crib for Use by Physically Disabled Parents. O'Riain MD, Layeux G, *Proceedings of ICAART 88*, 242-243, Montreal, 1988.

Two Systems to Enable Physically Disabled Persons to Board Inter-City Buses

Micheal D. O'Riain, PhD, PEng; Louis Goudreau, BASc; Ray Cheng, BASc, MHSc; Gilbert Layeux, Reg Tech; Harold Gay, Reg Tech
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Sponsor: *The Royal Ottawa Health Care Group; Transport Canada*

Purpose—The purpose of this project was to design and construct two systems which would enable physically disabled persons to board standard inter-city buses. The two systems (chosen from the original three designs submitted to Transport Canada) are as follows: 1) a ramp to be used to bring a special chair beside the first row of seats of the bus; and, 2) a stair lift system based on commercially-available units used in people's homes.

Progress—Our studies have indicated that the best strategy to get physically disabled persons into inter-city buses starts off with a transfer from the client's own wheelchair to a special wheelchair which is small enough to get through the bus entrance. This transfer is done at the most convenient location for both client and attendant. A suitable chair has been designed and constructed. Its height is adjustable to allow for level transfers for different wheelchair heights and different bus seat heights. One of the two boarding systems is then used to get the chair into the bus. Operational models of the two bus-boarding systems are presently under construction at our centre.

Future Plans—The operational models of the two systems will be completed, tests will be performed to determine the usefulness and function of the models, and designs will be made for the final production models of the boarding systems.

Microcomputer Techniques to Assist Dyslexia

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Sponsor: *None Listed*

Purpose—In this project, an investigation is being conducted into how techniques, similar to those which have been developed for the physically handicapped, could be modified to assist those with spelling and other cognitive disabilities. This is a joint project with the Psychology Department of Dundee University.

Microcomputers in Occupational Therapy

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Sponsor: *Scottish Home and Health Department*

Purpose—Occupational therapy consists of using activities to help people with disabilities to learn or relearn skills. The research project at the Microcomputer Centre is primarily interested in the use of computer programs as therapeutic activities. Researchers have examined applications in a wide range of areas of occupational therapy. The client groups that have been studied are head and hand injured patients, psychiatric patients, pediatric patients, the mentally handicapped and amputees.

The way in which microcomputer-based training is used varies greatly depending upon the needs of the patient. This is true within any one of the categories mentioned. In general, a program is used to encourage the client to develop or use a skill with which he or she has problems. The computer is a particularly good vehicle for this type of training, because material can be highly stimulating. In addition, computer programs can be very flexible, and so may be altered to suit the particular needs of an individual patient, while at the same time giving a repeatable measure of performance. As well as providing vehicles for practicing skills, computer programs can be used as "facilitators," to assist the therapist in encouraging the patient to participate in other aspects of treatment, as a basis for social activities for patients in long-stay institutions, and as aids in the assessment of clients' abilities. This flexibility as well as other features, means that the microcomputer can be a very useful therapeutic activity.

This application of microcomputer technology is still a comparatively new one, and occupational therapists still do not have programs which are entirely suitable to all their needs. The major effort of the research project at Dundee has been to develop new programs in close cooperation with occupational therapists, then to study the way in which these programs are used in clinical settings.

Future Plans—Therapists from without the area have frequently expressed interest in programs developed at the Microcomputer Centre. The sale of some software through a local educational software publisher has therefore been arranged. Researchers are also involved in courses for occupational therapists and other professionals working in this field, and video tapes have been produced to complement this work.

Application of Microcomputer Techniques in Special Education

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Sponsors: *Tayside Region Education Department; Scottish Education Department; Department of Trade and Industry, Scotland*

Purpose—The systems that have been developed in the Microcomputer Centre primarily for the rehabilitation of the disabled also have potential within education. A trained teacher will examine the applications of these systems to special education, particularly of the physically disabled, but also for those with perceptual problems and special learning difficulties. Recommendations will be made of the effectiveness of the systems, and they will be further developed to cope with particular problems that arise, and their capabilities expanded so that they may become more effective within education.

The Application of Artificial Intelligence Techniques for the Disabled

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Sponsor: *The TSB Foundation*

Purpose—A computer scientist with a special expertise and interest in artificial intelligence (AI) techniques is investigating the application of microcomputers to assist the disabled. The fellow will: 1) develop rule-base techniques for inducing spelling transformation; 2) apply natural language processing techniques to communication systems for the physically disabled; and, 3) have a general remit to advise on other projects and initiate new projects in the area of utilizing artificial intelligence techniques to assist the disabled. In particular, there will be a significant AI input to the projects on predictive typing aids and computer-based conversational systems for the speech impaired.

Rehabilitation Engineering Center

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Sponsor: *Texas Department of Mental Health and Mental Retardation; National Science Foundation*

Purpose—This program is designed to provide onsite rehabilitation engineering consultation and service delivery at selected state Mental Health and Mental Retardation (MHMR) facilities. It brings University engineering faculty and students in contact with MHMR personnel and clients for the definition, selection, and execution of design projects which will benefit individual clients, serve as a prototyping activity for client devices needed by a group of individuals, or be used within the facility for client treatment or education. The National Science Foundation (NSF) funding supports the design work of undergraduate students undertaken as part of the regular coursework or as special projects.

Progress—This report reflects 18 months of the program. Preliminary efforts consisted of meetings at each facility to acquaint the respective staffs with the nature of the program and the types of projects which were consistent with time frames and available resources to produce the designs.

Results—Projects to date include the design of a multipurpose adjustable wheelchair frame which could accommodate several devices used by the client. A headwand-operated joystick controller and speech synthesizer were also modified to make them more useful to the client. Seating problems were addressed to provide greater stability to a variety of clients, so that other activities and training could be more effective. Several communication devices for non-verbal and motor-limited clients were developed which allow for very simple selection from an intentionally limited menu. A variety of input devices to the communication systems were developed ranging from simple switch activation to foot operation. Similar systems for educating developmentally-delayed children were also provided which could accommodate both pictures and real objects for selection by the child at the direction of the therapist. A custom table to accommodate this type of system was designed and built which provides added stability for the child using the device. Additional projects included an arm-operated aerobic exercise machine; a child-size tricycle exercise bike; several types of interfaces between clients and typical environmental devices; and training devices which provide a reward feedback in the form of operation of a radio or similar appliance. A variety of innovative physical therapy and occupational therapy equipment has also been designed. Sheltered workshop task design problems were also addressed to improve workers' efficiency and to bring new contracts to the workshop. Non-design activities include general consultation with therapists in the application of commercially-available rehabilitation and general consumer equipment.

Future Plans/Implications—Experience with this program has demonstrated that there is a significant need for engineering design input for a wide variety of client problems at these facilities, and that many of these needs can be expediently met by a visiting or on-call engineering team. This service delivery model has distinct advantages in that continuous on-site engineering services could not be effectively utilized by these facilities at this time. Moreover, this program brings an array of expertise and experience to each facility as well as the resources of the University for fabricating selected projects. Future plans include expanding the program to cover more state and school facilities. As further experience and projects are generated, technology transfer between the needs of the various facilities, and short course technology training for on-site therapists will also be developed. The broad implications of this effort are that coordination of activities between state and other public agencies can efficiently enhance their programs. For the engineering student, this program provides an opportunity to solve real-world problems, obtain exposure to rehabilitation engineering, and gain a deeper understanding of individuals with handicaps and their needs.

Longitudinal Study of Public Expenditures for Services to the Handicapped

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Evaluation and Public Policy Analysis Program, Institute for the Study of Developmental Disabilities,
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Sponsors: *Office of Human Development, Department of Health and Human Services;*
National Institute on Disability and Rehabilitation Research

Purpose—The Evaluation and Public Policy Analysis Program conducts research on state and federal policies in mental retardation/developmental disabilities (MR/DD) services, and has developed extensive databases on state government expenditures for the decade from fiscal year (FY) 1977 through 1986. Also analyzed were federal government expenditure data spanning FY 1935 to 1985 for 82 separate programs. The third component of the study analyzed total (federal, state, and local) MR/DD expenditures.

Progress—The study's methodology consisted of the collection of state budget documents from the Council of State Governments in Lexington, KY, and in Washington, DC, and from the Center for Research Libraries in Chicago; documents were also obtained directly from the states, and extensive contacts with state officials augmented and confirmed data obtained from published sources. Comprehensive monographs were distributed to state and federal officials and to state advocacy organizations to encourage thorough review of analytical results prior to the publication of journal articles.

Results—A major finding of the study over-all was the extensive Federal Medicaid support from the Intermediate Care Facility for the Mentally Retarded (ICF/MR) program devoted to large congregate institutions (87 percent of federal ICF/MR dollars in FY 1986). This finding has significant implications in Congressional discussions of Medicaid Reform (the Community and Family Living Amendments). The State Government analysis also documented the continuing steady decline in average daily population of public MR/DD institutions, a recent increase in federal ICF/MR support for small, community-based services, and a declining level of federal support for community services from the Title XX/Social Services Block Grant.

The Federal Government analysis noted that since the 1950's MR/DD spending as a share of the total federal budget has grown rapidly, consisting primarily of income maintenance (Supplemental Security Income and Adult Disabled Child payments) and services programs (ICF/MR, special education and vocational rehabilitation). However, federal support of training and research for MR/DD has declined rapidly in real dollar terms since the early 1970's. The third component indicated that nearly $17 billion in federal, state, and local funds were deployed for MR/DD services in FY 1984.

Publications Resulting from This Research

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Financing Mental Retardation Programs in the United States: A Review of Recent Trends. Braddock D, in *Report to the President: President's Committee on Mental Retardation 20th Anniversary Symposium*, 52-61, Washington, DC, 1988b.

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Public Expenditures for Developmental Disabilities: Analyses of Nationwide Trends in Funding. Braddock D, Haney J, Hemp R, Fujiura G, in *Integration of Developmentally Disabled Individuals into the Community* (2nd ed.), 69-87, L. Heal, J. Haney, A. Amado (Eds.), Baltimore: Brookes Publishing Company, 1988.

Section II
Sponsor Index with Selected Program Summaries

Part A. Veterans Administration

Rehabilitation Research and Development Service
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Margaret J. Giannini, M.D., Director, and Deputy Assistant Chief Medical Director for Prosthetics and Rehabilitation

The mission of the Rehabilitation Research and Development Service program is to improve the quality of life of disabled veterans by making them more functionally independent. This mission is advanced through ongoing research projects in such priority areas as prosthetics/amputation, spinal cord injury, and sensory aids. Areas of special emphasis include aging, physical fitness, and psychosocial rehabilitation (e.g., dementia, schizophrenia, Alzheimer's disease, etc.).

During FY 1988, 183 rehabilitation R&D projects, including pilot projects, interagency studies, and special projects were conducted at 54 VA Medical Centers, including the two Rehabilitation Research and Development Centers at Hines, IL, and Palo Alto, CA, and the Atlanta Rehab R&D Unit in Decatur, GA.

In the areas of prosthetics, amputation, and orthotics, VA sponsored researchers are continuing to test new materials and using computer technology such as CAD/CAM to develop a new generation of artificial limbs. For spinal cord injuries, the use of robotics continues to be studied, as does the possibility that computer-controlled electrical stimulation can be used to restore function to paralyzed limbs. Research projects in the area of sensory aids include the continuing development of advanced mobility aids for visually-impaired people, digital hearing aids for those with hearing impairment, and various studies on treatment strategies and communication systems for aphasic individuals.

The VA Rehabilitation Research and Development Service sponsors a national program to review proposals submitted by researchers in the rehabilitation field. The Scientific Review and Evaluation Board for Rehabilitation Research and Development and Ad Hoc members assess proposals for their scientific/technical merit, budgetary needs, and time requirements. In 1988, the Board reviewed 97 proposals. There were 35 research projects approved in the three general priority areas. In addition, six pilot projects were approved to run for 1 year. Pilot projects are designed to test the feasibility of developing data, a technique, or a procedure prior to undertaking a regular research study.

The following are reports on the year's activities at the two R&D Centers and the R&D Unit.

Rehabilitation Research and Development Center
Edward A. Hines, Jr. VA Hospital
Hines, IL 60141

John Trimble, Ph.D., Director

Over the past year, the Rehabilitation Research and Development Center at Edward A. Hines, Jr. VA Hospital has developed into a major, regional resource for rehabilitation research. Our exceptional growth has dramatically increased our ability to fulfill our mission of providing disabled veterans with the concepts, devices and techniques that they need to lead productive and fulfilling lives. This growth is largely due to the renewal of our commitment to provide the type of cooperative, interdisciplinary research environment essential to innovative rehabilitation research. While the Rehabilitation R&D Center is the nucleus of this environment, new programs at the University of Illinois at Chicago and the University of Illinois at Urbana-Champaign provide the academic foundation essential for long-term growth. In many of the research areas that are central to our mission, these institutions have faculties comparable in skills and achievement to any in the world. Our affiliations with these institutions provide exceptional opportunities for interaction between rehabilitation professionals and researchers in the biological and behavioral sciences, the physical sciences, and engineering. They also provide us with access to unique resources such as the Division of Rehabilitation Education Services, the Beckman Institute for Advanced Science and Technology, and the National Center for Supercomputing Applications which have a profound impact on our ability to do truly innovative research. We have also developed other collaborative associations with Rush-Presbyterian St. Luke's Medical Center, the Illinois College of Optometry, the Illinois Visually Handicapped Institute, the University of Minnesota, and the Medical College of Wisconsin. These have also expanded the scope of our activities and provided important contributions to our mission. While we have placed considerable emphasis on expanding our research and development programs, we have not ignored efforts to transfer the results of these programs into practical devices, concepts or techniques.

In the past year, our Technology Transfer Program has gained considerable momentum. This momentum was established in October, 1988 by our conference on "Minority and Small Business Opportunities in Rehabilitation Technologies" which was attended by over 80 rehabilitation professionals, business people, venture capitalists, and people with disabilities. The interactions at this conference laid the foundation for subsequent collaboration with the Small Business Administration and the Inventors' Council, and the establishment of meaningful relationships with several manufacturers. These activities, together with the expansion of our research and development programs have made this a particularly productive year.

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Rehabilitation Research and Development Center
VA Medical Center
Palo Alto, CA 94303

Larry J. Leifer, Ph.D., Director

The Palo Alto Rehabilitation R&D Center continues to work to bring the finest engineering and medical science technology to veterans with physical or cognitive disabilities. It is our intent that new knowledge about disability, new methods of treatment, and new assistive devices will help lead to independent and productive lives.

Achievement of this objective is facilitated by affiliation with the Stanford University Schools of Engineering and Medicine. These and other collaborative associations are especially important to our mission. Collaborating institutions include NASA Ames Research Center, Massachusets Institute of Technology, University of Maryland, University of Santa Clara, University of California at Berkeley, University of California at Los Angeles, McGill University, Vanderbilt University, Delft University (Netherlands), Children's Hospital at Stanford, Santa Clara Valley Medical Center, American Foundation for the Blind, Smith-Kettlewell Eye Research Foundation, and the Paralyzed Veterans of America.

The Orthopaedic Biomechanics Program continues to be a leader in the analytic and experimental effort to develop a unified model for the relationship between mechanical strain energy and the growth, development, and eventual resorption of bone and cartilage. The validation of a unified theory has important implications for the design of joint replacement orthoses and for fracture healing. The Nerve and Muscle Systems Program continues to develop analytic models of nerve, muscle, and skeletal mechanics. In combination with electrophysiological and kinesiological experiments, these studies constitute a unique interdisciplinary synthesis. More importantly, they support optimal control strategies for the restoration of standing and walking through functional electrical stimulation. The Human-Machine Integration Program has completed several lines of device development (there are approximately 16 devices in the commercial product que). The group is now engaged in a strategic shift towards integration of artificial intelligence technology in mobility, manipulation, navigation, communication aids, and cognitive orthoses. Clinical studies in each of these areas have accounted for a large part of our effort during this past year. In particular, a third generation Desktop Vocational Assistant Robot has been placed in an off-station vocational field study and is ready for limited production.

Several devices and methodologies developed and/or reported in previous years have survived the arduous path from concept to production reality. New federal laws and renewed emphasis on a structured approach to technology transfer have helped to make this a particularly productive year.

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Atlanta Rehabilitation Research and Development Unit
VA Medical Center
Decatur, GA 30033

Franklyn K. Coombs, Director

The Unit is composed of four branches: Prosthetics, Biomaterials/Biomechanics, Neurophysiology, and Sensory and Behavioral Sciences. The Prosthetics branch conducts studies relating to artificial limbs, gait analysis, postural sway, wheelchairs, wheelchair cushions, and soft tissue mechanics. The Biomaterials/Biomechanics branch conducts studies relating to electrical stimulation for osteogenesis, artificial joints, and hard-tissue mechanics. The Neurophysiology branch studies vestibular functions, falls and the auditory aspects of balance, EEG analysis and sleep disorders, motor control systems, and incontinence. The Sensory and Behavioral Sciences branch studies visual and/or hearing impairment, spatial cognition, disorientation, wandering, wayfinding, and mobility.

The Unit conducted ten merit approved research projects during FY 1988, one of which had extramural support. Seventeen papers were published.

The Unit staff also conducted the following pilot studies with core funds:

Syme Ankle Prosthesis. The purpose of this study is to design and construct a prosthetic ankle joint for use by Syme amputees. An analysis of a natural ankle joint, the needs of amputees, strain energy calculations, and materials strength have been completed. Machining and construction plans to build several prototypes have also been completed.

Vestibular-Balance Testing. Researchers are planning studies in vestibular function and maintenance of equilibrium in normal and sensory-impaired individuals. Of particular interest is the effect of vestibular problems on the likelihood of falling. A NeuroCom dynamic posturography test apparatus has recently been obtained. It allows scientists to test movement, coordination, and body sway under normal and conflicting sensory conditions. Such tests are helpful in differential diagnosis of disequilibrium due to loss of vestibular function, proprioceptive cue sensitivity, or brain injury (e.g., stroke).

Eye Tracking. Using newly-acquired eye movement testing equipment, researchers are determining the effect of eye movement strategies on task performance for a variety of functional skills. One skill of particular interest is pedestrian travel, in both normally-sighted and visually-impaired individuals. Eye movement researchers have tended to conduct basic research, and typically have not addressed the need for work on rehabilitation-related questions. Several studies are being initiated to address this need. Eye movement should prove useful as an objective measure of the way individuals acquire visual information for performance of a variety of daily living tasks.

Dynamic Postural Sway and Floor Resiliency Assessment. A triaxial accelerometer is being used to quantify postural sway. This involves measuring the deviations from the vertical axis in the medio-lateral and antero-posterior planes of subjects during ambulation. Ultimately, the accelerometer will be used to predict the potential for falls among elderly persons. Once an integrated computer system for measuring postural sway has been developed, the effect of floor resilience on postural instability can be studied. This research will enable us to recommend the most appropriate flooring materials for minimizing fall injuries.

Situational Contributions to Falls. This study will identify the contribution of situational (environmental, social, behavioral) factors to falls among elderly persons. Information about falls will be obtained through video recordings, personal interviews, and nursing staff reports. With this information, it may be possible to reduce the occurrence of falls through interventions such as changes in building design, maintenance/housekeeping procedures, routine behavior patterns, and/or staff training.

Information Needed by Visually-Impaired People for Orientation and Wayfinding. This project will identify the type of environmental information that elderly visually-impaired people require or desire for effective orientation and wayfinding. Subjects will negotiate three test routes which vary in the amount and types of information provided, and the types of information from which they can make a selection as needed. The long-term result of this research will be to develop an automated travel-aid device to enhance wayfinding skills.

Evaluation of the Tai Chi Chaun Exercise. This study will determine the physiological and psychological effects of a six-month Tai Chi Chaun exercise program on elderly people. Pronounced as "tie-jee chwan," this exercise is being studied for the following reasons: it can be easily adapted to various disability groups and ages; it requires little space; and only loose-fitting clothing and flat-heeled shoes are needed.

Effectiveness of Assertiveness Training on Depression. This study will evaluate the impact of assertiveness training on relieving depression. This is an important study since depression is one of the most prevalent problems affecting the elderly.

Socioeconomic Status of the Elderly. While socioeconomic status is one of the most frequently used variables in gerontological research, traditional measures of socioeconomic status may not accurately reflect the class and status of the elderly. This study will develop an instrument to assess that status. Amelioration of the problems in measuring socioeconomic status is essential to identifying the quality of life of elderly people.

Laboratory Resource Developments

Vision. The vision laboratory is being developed to provide support for a variety of basic and applied research in visual perception and function. Equipment on hand includes devices for measuring dynamic and static visual acuity, visual fields, and sensitivity to contrast. Equipment to support the study of oculomotor function and distance and depth perception will also be obtained. Several innovative measures of accommodative response, distance and depth judgments, and contrast sensitivity are currently being developed to compare visual function and performance between younger and older observers who have no organic pathology. The emphasis of this research is to relate traditional clinical measures of visual function with the more behaviorally-based measures and to test the observers' responses to visual environments abstracted from real world situations. In future phases of the research, subjects manifesting typical age-related visual pathologies such as macular degeneration, glaucoma, and cataracts will be compared with the normative population under current study.

Audition. Laboratory resources will support a variety of basic and applied research in audition and psychoacoustics. They include test apparatus for pure tone sensitivity, free-field sound localization, and detection of sound shadow. Studies will also be conducted to determine echolocation and spectral shape.

Video Analysis. The video analysis laboratory permits behavioral researchers to obtain detailed and accurate observational data through the use of video tape. Relevant data are edited onto composite tapes and these tapes are scored a sufficient number of times by multiple viewers to obtain statistical reliability. Consisting of a multiple-camera surveillance package with time-lapse recorders, detection devices, audio, and infra-red viewing capabilities, the system is particularly useful in studying infrequent events such as falls or wandering patterns of the elderly in a nursing home.

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Margaret Brown, Director of Research

The American Paralysis Association is a nonprofit organization that funds research in the area of spinal cord injury, with emphases on neural regeneration, prevention of secondary neuronal damage, and cures for chronic paralysis (especially paralysis consequent to spinal cord injury).

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The Moss Rehabilitation Center of the hospital conducts work in innovative prosthetic design, gait analysis, neuropsychology, motor control, and clinical neurophysiology.

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National Institute on Disability and Rehabilitation Research
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Established by the 1978 amendments to the Rehabilitation Act, the National Institute on Disability and Rehabilitation Research (NIDRR) is responsible for managing a comprehensive program of disability-related research and training for professionals who provide services and conduct research. NIDRR's mandate encompasses all major areas of applied research, such as medicine (including basic medical research); vocational rehabilitation; children, families, and other areas of psychosocial research; rehabilitation engineering; and information dissemination. All disabilities and age groups are at least potentially included in NIDRR research endeavors. The ultimate goal of NIDRR-sponsored projects is to enhance the independence of disabled persons and facilitate their full integration into all aspects of community life.

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The Bioengineering and Research to Aid the Handicapped (BRAH) program of the National Science Foundation emphasizes fundamental research that will support the emergence of medical-engineering technologies, especially technologies with the potential to become medically valuable within ten years.

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The Natural Sciences and Engineering Research Council is Canada's largest research granting agency. While it does not target its research directly in the area of rehabilitation, the Council does fund research in the engineering of prosthetic devices and artificial limbs, as well as research in computing, communications, and instrumentation technology.

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The Spinal Cord Research Foundation (SCRF) was founded by the Paralyzed Veterans of America in 1975. SCRF sponsors basic research projects and fellowships that are designed to increase scientific knowledge toward a cure for spinal cord injury. SCRF also funds research that deals with applied medical, psychosocial, and technological areas of importance to persons with spinal cord injury.

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VA REHABILITATION DATABASE: THE DREAM

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